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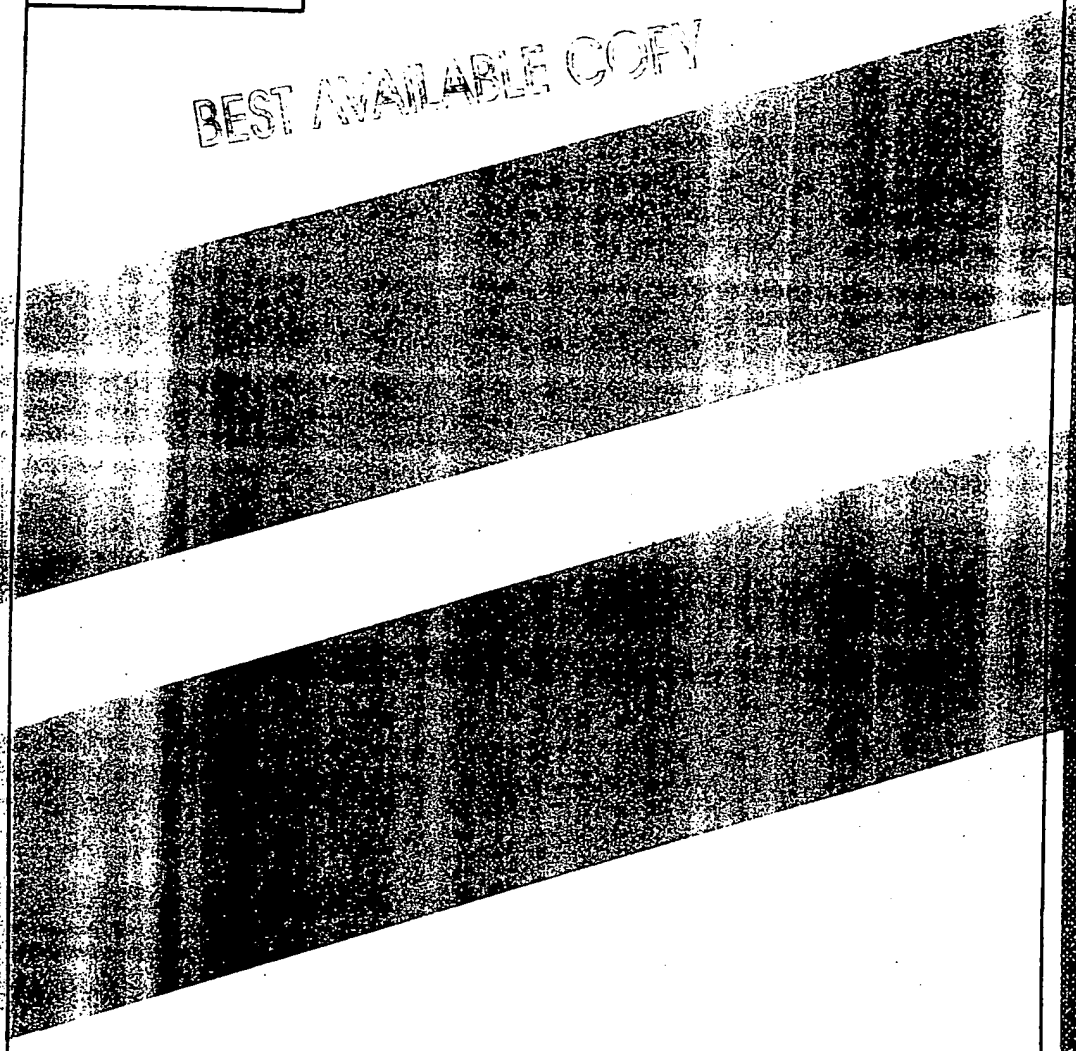

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APPLICANT

GREGORY H. LAMBRECHT, NATICK, MA.

CONTINUING DOMESTIC DATA********
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Foreign Priority claimed 35 USC 119 (a-d) conditions met ☐yes ☐no ☐Met after Allowance Verified and Acknowledged _____ Examiner's Initials	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
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ADDRESS

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TITLE

METHODS AND DEVICES FOR INTERVERTEBRAL DISC REPAIR

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Gregory H.	Lambrecht	220 Eliot Street, Natick MA

☐ *Additional Inventors are being named on the ___ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

Methods And Devices For Intervertebral Disc Repair

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

☐ Customer Number ☐ → *Type Customer Number here*

OR

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages*	22	☒ Small Entity Statement	
☒ Drawing(s) *Number of Sheets*	21	☒ Other (specify)	Cover Sheet - 1 page

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT *(check one)*

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Respectfully submitted,

SIGNATURE _____

Date 12/13 / 99

TYPED or PRINTED NAME Gregory H. Lambrecht

REGISTRATION NO. *(if appropriate)* ☐

Docket Number: ☐

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C., 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C., 20231.

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))—INDEPENDENT INVENTOR	Docket Number (Optional)

Applicant, Patentee, or Identifier: Greg Lambrecht

Application or Patent No.: Provisional Patent Application

Filed or Issued: Filed 12/13/99

Title: Methods And Devices For Intervertebral Disc Repair

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

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Gregory H. Lambrecht		
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of Inventor	Signature of Inventor	Signature of Inventor
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APPLICATION

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SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Gregory H. Lambrecht, a U.S. citizen, residing in Natick, MA, has invented certain improvements in METHODS AND DEVICES FOR INTERVERTEBRAL DISC REPAIR which the following description in connection with the accompanying drawings is a specification, like reference characters on the drawings indicating the parts in the several figures. The following specification is a continuation of Application Number 60/161,085 filed on October 25, 1999.

Title

Methods And Devices For Intervertebral Disc Repair

Inventor

Greg Lambrecht

Background

The present invention relates to the surgical treatment of intervertebral (IV) discs in the lumbar, cervical, or thoracic spine that have suffered from herniation or significant disc height loss.

Herniation of an IV disc is one of the ten most common diagnoses in the United States. The disc performs the important role of absorbing mechanical loads while allowing constrained flexibility of the spine. The disc is composed of a soft, central nucleus pulposus (NP) surrounded by a tough, woven anulus fibrosus (AF). Herniation is a result of a weakening in the AF. Symptomatic herniations occur when weakness in the anulus fibrosis allows the NP to bulge or leak posteriorly toward the spinal cord and major nerve roots. The most common resulting symptoms are pain radiating along a compressed nerve and low back pain, both of which can be crippling for the patient. The significance of this problem is increased by the low average age of diagnosis, with over 80% of patients in the U.S. being under 59.

Prior Art

Since its original description by Mixter & Barr in 1934, discectomy has been the most common surgical procedure for treating IV disc herniation. This procedure involves removal of disc materials impinging on the nerve roots or spinal cord posterior to the disc. Depending on the surgeon's preference, varying amounts of NP is then removed from within the disc space either through the herniation site or through a surgical incision in the AF. This removal of extra NP is commonly done to minimize the risk of recurrent herniation.

Nevertheless, the most significant drawbacks of discectomy are recurrence of herniation, recurrence of radicular symptoms, and increasing low back pain. Re-herniation can occur in up to 21% of cases. The site for re-herniation is most commonly the same level and side as the previous herniation and can occur through the same weakened site in the AF. Persistence or recurrence of radicular symptoms happens in many patients and when not related to re-herniation, tends to be linked to stenosis of the neural foramina caused by a loss in height of the operated disc. Debilitating low back pain occurs in roughly 14% of patients. All of these failings are most directly related to the loss of NP material and AF competence that results from herniation and surgery.

Loss of NP material deflates the disc, causing a decrease in disc height. Significant decreases in disc height have been noted in up to 98% of operated patients. Loss of disc height increases loading on the facet joints. This can result in deterioration of facet

cartilage and ultimately c oarthritis and pain in this joint. As th nt space decreases the neural foramina formed by the inferior and superior vertebral pedicles also close down. This leads to canal stenosis, pinching of the traversing nerve root, and recurring radicular pain. Loss of NP also increases loading on the remaining AF, an innervated structure that can produce pain. Finally, loss of NP results in greater bulging of the AF under load. This can result in renewed impingement by the AF on nerve structures posterior to the disc.

Persisting tears in the AF that result either from herniation or surgical incision also contribute to poor results from discectomy. The AF has been shown to have limited healing capacity with the greatest healing occurring in its outer borders. Healing takes the form of a thin fibrous film that does not approach the strength of the uninjured disc. Surgical incision in the AF has been shown to produce immediate and long lasting decreases in stiffness of the AF particularly against torsion loads. This may over-stress the facets and contribute to their deterioration. Further, in as many as 30% of cases, the AF never closes. In these cases, not only is re-herniation a risk but also leakage of fluids from within the NP into the epidural space can occur. This has been shown to cause localized pain, irritation of spinal nerve roots, decreases in nerve conduction velocity, and may contribute to the formation of post-surgical scar tissue in the epidural space.

Other orthopedic procedures involving removal of soft tissue from a joint to relieve pain have resulted in significant, long lasting consequences. Removal of all or part of the menisci of the knee is one example. Partial and total meniscectomy leads to increased osteoarthritic degeneration in the knee and the need for further surgery in many patients. A major effort among surgeons to repair rather than resect torn menisci has resulted in more durable results and lessened joint deterioration.

To date, there have been very few attempts to repair the IV disc. Yasargil mentions suturing the AF closed after complete removal of the NP, but does nothing to limit disc height loss or posterior bulging of the AF.

There are numerous ways of augmenting the IV disc disclosed in the art. In reviewing the art, two general approaches are apparent – implants that are fixed to surrounding tissues and those that are not fixed, relying in stead on the AF to keep them in place.

The first type generally replace the entire disk, such as Stubstad in US 3,867,728, Frey in US 4,932,969, and Stone in U.S. 5,108,438. These concepts are limited in many ways. First, by replacing the entire disc they generally must endure all of the loads that are transferred through that disc space. Many degenerated discs are subject to pathologic loads that exceed those in normal discs. Hence, the designs must be extremely robust and yet flexible. None of these devices has yet been able to achieve both qualities. Further, devices that replace the entire disc must be implanted using relatively invasive procedures, normally from an anterior approach. They may also require the removal of considerable amounts of healthy disc material including the anterior AF. Further, the disclosed inventions must account for the contour of the neighboring vertebral bodies to which they are attached. Because each patient and each vertebra is different, these types of implants must be available in many sizes.

The second type of augm. .tion involves an implant that is not d. .y fixed to surrounding tissues. Examples include Ray's US 5,824,093, Felt's US 5,888,220, Krapiva's US 5,645,597, Bao's patents US 5,047,055 and US 5,192,326 and Baumgertner's series of patents US 5,702,454, US 5,171280, EP 0621020A1, and EP 0453393A1. These inventions rely on an AF that is primarily intact to hold them in place. The disclosed implants are generally inserted through a hole in the AF and either expand, are inflated, or deploy expanding elements so as to be larger than hole through which they are inserted. The limitation of these concepts is that the AF is often not intact in cases requiring augmentation of the disc. There are either rents in the AF or structural weaknesses that would allow herniation or migration of the disclosed implants. In the case of a disc herniation, there are definite weaknesses in the AF that allowed the herniation to occur. Augmenting the NP with any of the above disclosed inventions without supporting the AF or implant risks re-herniation of the augmenting materials. Further, those inventions with deployable elements such as Ray's US 5,824,093 and Baumgarner's US 5,702,454 risk indiscriminately injuring the vertebral endplates or the AF. Many of the patents describe closing the AF at the site of insertion. This may help, but again herniations do not require a rent in the AF. Structural weakness in or delamination of the multiple layers of the AF can allow these implants to bulge toward the posterior neural elements. Additionally, as the disc continues to degenerate, rents in the posterior anulus may occur in regions other than the original operated site. A further limitation of these concepts is that they require the removal of much or all of the NP to allow insertion of the implant. This requires time and skill to achieve and may permanently alter the physiology of the disc.

There are numerous devices and methods disclosed in the art for closing defects in body walls or vessels. These devices and methods are employed to prevent the movement of materials across the defects. Each has its own limitation if applied to the intervertebral disc.

Most of the art relates to the closure of hernias through the abdominal wall. Disclosed devices include either planer patches applied to the interior of the abdominal wall or plugs that are placed directly into the defect. Examples of the former include Eberbach (US 5,122,155 and US 5,366,460), Gianturco (US 5,258,000), DeMatteis (US 5,383,477), de la Torre (US 5,368,602), Kugel (US 5,769,864 and US 5,916,225), and Mulhauser et al. (US 5,766,246). Each describes a planar patch with our without a stiffening element or delivery tool to bias the patch into a planar configuration. Such devices are limited in their application in the intervertebral disc by the disc's geometry. The interior aspect of the AF is curved in multiple planes, making a flat patch incongruous to the surface against which it must seal. These devices are further limited by the instruments or stiffening elements incorporated into the periphery of the patch. The disc height is rarely greater than 5mm. With a peripherally supported patch, two segments of such elements would span any given location along the patched surface. This requires that each stiffening element have a thickness along the height of the disc of less than 2.5mm, making them considerably weaker than the central enlarging means disclosed in this invention. Finally, the prior art discloses patches that are placed into a cavity that is either distended by gas or supported such that the interior wall of the defect is held away from internal organs. In the disc, it is difficult to create such a cavity between the inner wall of the anulus and the NP without removing nucleus material. Such removal may be detrimental to the clinical outcome of disc repair.

Butkow et al. disclose an exemplary plug in US 5,356,432. This plug may be adequate for treating inguinal hernias, due to the low pressure difference across such a defect. However, placing a plug into the AF that much resist much higher pressures may result in expulsion of the plug or dissection of the inner layers of the anulus by the NP. Either complication would lead to extraordinary pain or loss of function for the patient. Further, a hernia in the intervertebral disc is likely to spread as the AF progressively weakens. In such an instance, the plug may be expelled into the epidural space.

Pajotin et al. in US 5,954,767 discloses a curved prosthetic mesh for use in inguinal hernias. Pajotin describes a sheet of material that has a convex side and a concave side and further embodiments with both spherical and conical sections. This device may be well suited for inguinal hernias, but the shape and stiffness of the disclosed embodiments are less than optimal for application in hernias of the intervertebral disc. Hernias tend to be broader (around the circumference of the disc) than they are high (the distance between the opposing vertebrae), a shape that does not lend itself to closure by such conical or spherical patches.

Wilk et al. disclose an inflatable, barbed balloon patch used for closing inguinal hernias. This balloon is left inflated within the defect. A disadvantage of this embodiment is that the balloon must remain inflated for the remainder of the patient's life to insure closure of the defect. Implanted, inflated devices rarely endure long periods without leaks, particularly when subjected to high loads. This is true of penile prostheses, breast implants, and artificial sphincters.

Sheffield et al. (US 5,972,007) disclose another method of closing inguinal hernias. The method involves applying both heat and pressure to a planar patch and the abdominal wall surrounding the hernia. This invention has the drawback of relying entirely on the integrity of the wall surrounding the defect to hold the patch in place. The anulus is often weak in areas around a defect and may not serve as a suitable anchoring site. Further, the planar nature of the disclosed patch has all of the weaknesses discussed above.

Various devices and techniques have further been disclosed for sealing vascular puncture sites. The most relevant include those disclosed by Kensey et al. and Stack. Kensey et al. disclose a hemostatic puncture sealing device that generally consists of an anchor, a filament and a sealing plug. The anchor is advanced into a vessel through a defect and deployed such that it resists passage back through the defect. A filament leading from the anchor and through the defect can be used to secure the anchor or aid in advancing a plug that is brought against the exterior of the defect. Exemplary patents in this series include US 4,731,330, US 4,890,612, and US 5,545,178. These disclosures employ a filament brought back through the defect. Such a filament, if it were to extend to the exterior of the disc, could lead to irritation of nerve roots and the formation of scar tissue in the epidural space. This is also true of any plug material that may be left either within the defect or extending to the exterior of the disc. Stack (US 5,342,393) has the same shortcoming in that the exterior portion of the disclosed rivets could abrade nerve tissue and lead to pain and scar formation within the epidural space. Additionally, both Kensey and Stack disclosures are embodied for use in the vascular system and would be hard to implement in the disc. Both require a space relatively empty of solids for the deployment of the interior anchor. This works well on the interior of a vessel. However, in the

presence of the more sub: .ial NP, the disclosed internal anchor. . unlikely to orient across the defect as disclosed in their inventions.

It is the object of the present invention to overcome the many limitations of the described prior art. It is a further object of this invention to reduce the long-term negative consequences of herniated discs by repairing and/or augmenting rather than resecting the soft tissues of the disc. It is a further object of this invention to prevent or reduce the occurrence of re-herniation and disc height loss following surgical therapy for herniated IV discs. It is a further object of this invention to increase the AF's resistance to posterior bulging and leakage of NP material while increasing its stiffness under load. It is a further object of this invention to permit the augmentation of the soft tissues of the disc in such a way as to limit the risk of the herniation of any augmentation materials toward nerve structures posterior to the disc.

Summary Of The Invention

The present invention relates to devices and methods for sealing defects in tissue walls separating two anatomic regions of the body. Specifically, devices and methods are disclosed which allow the closure of a defect in the AF of the human intervertebral disc, preventing the egress of material from within the disc.

Each aspect of the present invention relates to placing a barrier means on an interior aspect of the defect. In the case of the intervertebral disc, the barrier means is positioned on the interior aspect of the AF proximate to the NP. The barrier means may be inserted by dissecting a space between the anulus and nucleus. Alternatively, a portion of the nucleus and/or anulus may be resected to create adequate space.

The barrier means may be inserted into position directly through the defect or alternatively it may be advanced from a remote entry through the tissue wall or another tissue neighboring the defect.

Various fixation means can be used to secure the barrier means to surrounding tissues. In the IV disc, these tissues can included the surrounding AF, vertebral endplates, vertebral bodies, and even NP. Alternatively, the barrier means may be held in place simply by the pressure the NP exerts on the barrier means and AF. The barrier means may further incorporate various self-retaining members that resist motion of the barrier means within the disc. Separate fixation means may also be employed to secure the barrier means to surrounding tissues. The barrier means may incorporate an enlarging or expanding means that acts to increase the dimensions of the barrier means from a compressed state to an enlarged state. The barrier means may further have properties that cause it to adhere to surrounding tissues upon the application of heat.

Various embodiments of the disclosed barrier means are composed of either singular materials and components or a multiplicity of materials and components.

Description Of The Figures

Figure 1 depicts intervertebral disc 15 comprising nucleus pulposus 20 and anulus fibrosis 10. Nucleus pulposus 20 forms a first anatomic region and extra-discal space 500 (any space exterior to the disc) forms a second anatomic region wherein these regions are separated by anulus fibrosus 10 (a body wall).

Figure 1A is an axial (transverse) view of the intervertebral disc 15. Posterior lateral defect 40 in anulus fibrosis10 has allowed segment 30 of nucleus pulposus 20 to herniate into an extra discal space 500. Interior aspect 50 and exterior aspect 60 are shown, as are the right 70' and left 70 transverse processes and posterior process 80.

Figure 1B is a sagittal section along the midline intervertebral disc 15. Superior pedicle 90 and inferior pedicle 90' extend posteriorly from superior vertebral body 95 and inferior vertebral body 95' respectively.

Figure 2A is an axial view of the intervertebral disc 15 with the right half of sealing means 1 of a barrier means being placed against the interior aspect of a defect in anulus fibrosis 10 by a dissection/delivery tool 100.

Figure 2B is the same view as Figure 2A with the full sealing means 1 placed on the interior aspect of a defect in anulus fibrosis 10.

Figure 3A depicts sealing means 1 of Figure 2B being secured to tissues surrounding the defect by fixation means 2 passed through an opening into an interior cavity within sealing means 1 by fixation device 100.

Figure 3B depicts sealing means 1 of Figure 3A after two fixation means 2 have been passed into surrounding tissues. The fixation device 100 has been removed from the disc.

Figure 4A depicts an axial view of sealing means 1 of Figure 3B after enlarging means 3 has been inserted into the interior cavity of sealing means 1 through an opening.

Figure 4B depicts the construct of Figure 4A in a sagittal section. The pair of fixation means 2 are shown piercing into superior vertebral body 95 and inferior vertebral body 95'.

Figure 5A shows an alternative fixation scheme for sealing means 1 and enlarging means 3 depicted in the previous figures. Fixation region 4 of enlarging means 3 is shown protruding from the sealing means 1 in a region spanning the defect.

Figure 5B shows the construct of Figure 5A in a sagittal section with anchor 2' securing fixation region 4 of the enlarging means 3 to superior vertebral body 95 in a location proximate to the defect.

Figure 6A depicts embodiment 1' of the barrier means of the present invention being secured to anulus fibrosus 10 using fixation darts 5 and 5'. Fixation darts 5 and 5'are delivered by fixation tool 120, which enters anulus fibrosus 10 before delivering the

darts. This prevents any ion of fixation darts 5 and 5' from pr ding into second anatomic region 500.

Figure 6B depicts embodiment 1' of the barrier means of Figure 6A secured to anulus 10 by two fixation darts 5 and 5', wherein no aspect of the fixation darts extends into second anatomic region 500. Fixation tool 120 has been removed.

Figures 7A and 7B depict barrier means 6 positioned between layers of the anulus fibrosis 10 on either side of a defect. Figure 7A is an axial view while 7B is a sagittal cross section.

Figure 8 depicts a sagittal cross section of a large version of barrier means 1'. In this figure, barrier means 1' is positioned across the defect as well as the entirety of the posterior aspect of anulus fibrosis 10.

Figure 9 depicts a sagittal cross section of barrier means 1' in position across a defect following insertion of two augmentation devices 11. Barrier means 1' is secured to tissues surrounding the defect by fixation darts 5.

Figure 10 depicts the barrier means as region 300 of elongated augmentation device 12. Barrier region 300 is secured to tissues surrounding the defect by two fixation darts 5.

Figure 11 depicts a configuration of augmentation device 12' similar to that of Figure 10. In this embodiment, barrier region 300 extends across the defect and has fixation region 4 facilitating fixation of the device 12' to superior vertebral body 95 with anchor 2'. Figure 11A is an axial section while Figure 11B is a sagittal section.

Figures 12A-D depict deployment of barrier means 13 from entry site 800 remote from defect 40 in anulus fibrosis 10. For clarity, nucleus pulposus 20 is indicated but not shaded. Figure 12A shows insertion instrument 130 with a distal end positioned within the disc space occupied by nucleus pulposus 20. Figure 12B depicts delivery catheter 140 exiting the distal end of insertion instrument 130 with barrier means 13 on its distal end. Barrier means 13 is positioned across the interior aspect of the defect 40. Figure 12C depicts the use of expandable barrier means 13' wherein delivery catheter 140 is used to expand barrier means 13' with balloon 150 (not seen) on its distal end. Balloon 150 may exploit heat to further adhere barrier means 13' to surrounding tissue. Figure 12D depicts removal of balloon 150 and delivery catheter 140 from the disc space leaving expanded barrier means 13' positioned across defect 40.

Figure 13 depicts four of the many possible embodiments of the barrier means. Each embodiment exploits a sealing means 1 and an enlarging means 3 that may further add stiffness to the overall barrier means construct. Figure 13A is an elongated cylindrical embodiment with enlarging means 3 located about the long axis of the device. Figure 13B depicts a barrier means comprising an enlarging means 3 with a central cavity 9. Figure 13C depicts a barrier means comprising a non-axisymmetric sealing means 1. In use, the longer section of sealing means 1 as seen on the left side of this figure would extend between opposing vertebra 95 and 95'. Figure 13D depicts a barrier means comprising a non-axisymmetric sealing means 1 and enlarging means 3. The concave portion of the barrier means preferably faces nucleus pulposus 20 while the convex

surface faces the defect -. nd the inner aspect of the anulus fibr 10. This embodiment exploits pressure within the disc to compress sealing means 1 against neighboring vertebral bodies 95 and 95' to aid in sealing.

Figure 14 depicts cross sections of a preferred embodiment of sealing means 1 and enlarging means 3. Sealing means 1 has internal cavity 7 and opening 8 leading from its outer surface into internal cavity 7. Enlarging means 3 can be inserted through opening 8 and into internal cavity 7.

Figure 15 depicts an alternative configuration of enlarging means 3. Fixation region 4 extends through opening 8 in sealing means 1. Fixation region 4 has a through-hole that can facilitate fixation of enlarging means 3 to tissues surrounding defect 40.

Figure 16 depicts an alternative shape of the barrier means. In this embodiment either sealing means 1, enlarging means 3, or both have a curvature with radius R. This curvature can be used in any embodiment of the present invention and may aid in conforming to the curved inner circumference of anulus fibrosis 10.

Figure 17 is a section of a device used to affix sealing means 1 to tissues surrounding a defect (not shown). In this figure, sealing means 1 would be positioned across interior aspect 50 of defect 40. The distal end of device 110' would be inserted through defect 40 and opening 8 into the interior cavity 7. On the right side of this figure, fixation dart 2 has been passed from device 110', through a wall of sealing means 1 and into tissues surrounding sealing means 1. On the right side of the figure, fixation dart 2 is about to be passed through a wall of sealing means 1 by advancing pusher 111 relative to device 110' in the direction of the arrow.

Figure 18 depicts the use of thermal device 200 to heat sealing means 1 and adhere it to tissues surrounding a defect. In this figure, sealing means 1 would be positioned across the interior aspect 50 of a defect 40. The distal end of thermal device 200 would be inserted through the defect and opening 8 into interior cavity 7. In this embodiment, thermal device 200 employs at its distal end resistive heating element 210 connected to a voltage source (not shown) by wires 220. Covering 230 is a non-stick surface such as Teflon tubing that ensures the ability to remove device 200 from interior cavity 7. In this embodiment, device 200 would be used to heat first one half, and then the other half of sealing means 1.

Figure 19 depicts an expandable thermal element, such as a balloon, that can be used to adhere sealing means 1 to tissues surrounding a defect. Sealing means 1 is not shown. As in Figure 18, the distal end of device 130 would be inserted through the defect and opening 8 into interior cavity 7, with balloon 150' on the distal end device 130 in a collapsed state. Balloon 150' is then inflated to expanded state 150, expanding sealing means 1. Expanded balloon 150 could heat sealing means 1 and surrounding tissues by inflating it with a heated fluid or by employing RF electrodes (not shown). In this embodiment, device 130 would be used to expand and heat first one half, then the other half of sealing means 1.

Figure 20 depicts an alternative embodiment to device 130. This device employs an elongated, flexible balloon 150' that can be inserted into and completely fill internal

cavity 7 of sealing means 1 prior to inflation to an expanded state 2. Using this embodiment, inflation and heating of sealing means 1 can be performed in one step.

Description Of The Preferred Embodiments

In a preferred embodiment, the barrier means is placed into a space between the AF and the NP proximate to the inner aspect 50 of defect 40 as depicted in Figure 2. The space can be created by blunt dissection. Dissection can be achieved with a separate dissection instrument, with the barrier means itself, or a combined dissection/barrier means delivery tool 100. This space is preferably no larger than the barrier means such that the barrier means is in contact with both AF 10 and NP 20. This allows the barrier means to transfer load from NP 20 to the AF 10 when the disc is pressurized during activity.

In position, the barrier means preferably spans the defect and extends along the interior aspect 50 of the AF 10 until it contacts healthy tissues on all sides of the defect 40. Depending on the extent of the defect, the contacted tissues can include AF, cartilage overlying the vertebral endplates, and/or the endplates themselves. In another aspect of the present invention, the patch can be placed between two neighboring layers of AF on either side of the defect 40 as depicted in Figures 7A and 7B.

In the preferred embodiment, the barrier means consists of two components – a sealing means 1 and an enlarging means 3 (see Figures 13-16).

Sealing means 1 forms the periphery of the barrier means and has an interior cavity 7. There is at least one opening 8 leading into cavity 7 from the exterior of the sealing means 1. Sealing means 1 is preferably compressible or collapsible to a dimension that can readily be inserted into the disc through a relatively small hole. This hole may be the defect itself or a site remote from the defect. Sealing means 1 is constructed from a material and is formed in such a manner as to resist the passage of fluids and other materials around sealing means 1 and through the defect. Sealing means 1 may be constructed from one or any number of a variety of materials including, but not limited to PTFE, e-PTFE, Nylon, Marlex, and/or collagen.

Enlarging means 3 is sized to fit within cavity 7 of sealing means 1. It is preferably a single object of a dimension that can be inserted through the same AF defect through which sealing means 1 was passed. Enlarging means 3 expands sealing means 1 to an expanded state as it is passed into cavity 7. The purpose of enlarging means 3 is, at a minimum, to expand sealing means 1 to a size greater than that of the defect such that the assembled barrier means prevents passage of material through the defect. Enlarging means 3 may further impart stiffness to the barrier means such that the barrier means will resist the pressures within nucleus pulposus 20 and expulsion through the defect. Enlarging means 3 may be constructed from one or any number of materials including, but not limited to silicon rubber, various plastics, stainless steels or other metals. These materials may form a solid object, a hollow object, coiled springs or other suitable forms capable of filling cavity 7 within sealing means 1.

Sealing means 1, enlarging means 3, or the barrier means construct may further be affixed to tissues either surrounding the defect or remote from the defect. In the preferred embodiment, no aspect of the fixation means or the barrier means and its components

extends posterior to the ... (into the second anatomic region 500. This avoids the risk of contacting and irritating the sensitive nerve tissues posterior to the disc.

In a preferred embodiment, sealing means 1 is inserted into the disc proximate the interior aspect 50 of the defect. Sealing means 1 is then affixed to the tissues surrounding the defect using a suitable fixation means, such as suture or a soft-tissue anchor. The fixation procedure is preferably performed from the interior of the sealing means cavity 7 as depicted in Figures 3A, 3B and 17. A fixation delivery instrument 110, 110'is delivered into cavity 7 through opening 8 in sealing means 1. Fixation means 2 is/are then deployed through a wall of sealing means 1 into surrounding tissues. This method eliminates the need for a separate entryway into the disc for delivery of fixation means 2. It further minimizes the risk material leaking through sealing means 1 proximate to the fixation means 2. One or more fixation means 2 may be delivered into one or any number of surrounding tissues. Following fixation of sealing means 1, enlarging means 3 may be inserted into cavity 7 of sealing means 1 to further expand the barrier means construct as well as increase its stiffness as depicted in Figures 4A and 4B. Opening 8 into sealing means 1 may then be closed by suture or other means, although this is not a requirement of the present invention. In certain cases, insertion of a separate enlarging means may not be necessary if adequate fixation of sealing means 1 is achieved.

Another method of securing the barrier means to tissues is to affix enlarging means 3 to tissues either surrounding or remote from the defect. Enlarging means 3 may have an integral fixation region 4 that facilitates securing it to tissues as depicted in Figures 5A, 5B and 15. This fixation region may extend exterior to sealing means 1 either through opening 8 or through a separate opening. Fixation region 4 can have a hole through which a fixation means may be passed. In a preferred embodiment, enlarging means 3 is affixed to at least one of the surrounding vertebral bodies (95, 95') proximate the defect using a small bone anchor 2'. Alternatively, the enlarging means itself may have an integral fixation means located at a site or sites along its length.

Another method of securing the barrier means is to insert the barrier means through the defect or another opening into the disc, position it proximate the interior aspect of the defect 50, and pass at least one fixation means through anulus fibrosus 10 and into the barrier means. In a preferred embodiment of this method, fixation means 5 are first passed partially into anulus fibrosus 10 within a fixation device 120 such as a hollow needle. As depicted in Figures 6A and 6B, fixation means 5 are then advanced into the barrier means and fixation device 120 is removed. Fixation means 5 preferably has two ends, each with a means to prevent movement of that end of the fixation means. Using this method, the fixation means is lodged in both the barrier means and anulus fibrosis 10 without any aspect of fixation means 5 exterior to the disc in the second anatomic region 500.

Another method of securing the barrier means is to adhere it to surrounding tissues through the application of heat. In this embodiment, the barrier means includes a sealing means 1 comprised of a thermally adherent material that adheres to surrounding tissues upon the application of heat. The thermally adherent material can include thermoplastic, collagen, or a similar material. The sealing means may further comprise a separate structural material that adds strength to the thermally adherent material, such as a woven Nylon or Marlex. This thermally adherent sealing means preferably has an interior cavity

7 and at least one openi.. leading from the exterior of the barri. .eans into cavity 7. As depicted in Figures 12C, 12D, 18, 19, and 20, a thermal device 200, 130 can be inserted into cavity 7 and used to heat sealing means 1 and surrounding tissues. This thermal device is preferably a separate device that can be removed after the application of heat. This device can be a simple thermal element 210, such as a resistive heating coil, rod or wire. It may further be a number of electrodes capable of heating the barrier means and surrounding tissue through the application of radio frequency (RF) energy. The thermal device can further be a balloon 150, 150' capable of both heating and expanding the barrier means. Balloon 150, 150' can either be inflated with a heated fluid or have electrodes located about its surface to heat the barrier means with RF energy. Balloon 150, 150' is deflated and removed after heating the sealing means. These thermal methods and devices achieve the goal of adhering the sealing means to the AF and NP and potentially other surrounding tissues. The application of heat could further aid the procedure by killing small nerves within the AF, by causing the defect to shrink, or by causing cross-linking and/or shrinking of surrounding tissues. After the application of heat, a separate enlarging means 9 may be inserted into the interior cavity of the barrier means to either enlarge the barrier means or add stiffness to its structure. Such an enlarging means is preferably similar in make-up and design to those described above. Use of an enlarging means may not be necessary in some cases and is not a required component of this method.

The most suitable embodiment of the barrier means in the spinal application is a patch having a length (oriented along the circumference of the disc) that is substantially greater than its height (oriented along the height of the disc, i.e. the distance separating the surrounding vertebral bodies). The patch preferably has a primary curvature or gentle curve along the length of the patch that allows it to conform to the inner circumference of the AF. This curvature may have a single radius R as shown in Figure 16 or may have multiple curvatures. The curvature may be fabricated into the barrier means and/or any of its components. For example, the sealing means could be made without an inherent curvature while the enlarging means may have a primary curvature along its length. Once the enlarging means is placed within the sealing means the overall barrier means assembly takes on the primary curvature of the enlarging means. This modularity allows enlarging means with specific curvatures to be fabricated for defects occurring in various regions of the anulus.

The cross sectional shape of the barrier means can be any of a number of shapes, but preferably has a 'C' shape as shown in Figure 13D wherein the convex portion of the patch rests against the interior aspect of the AF while the concave portion faces the NP. To improved the sealing ability of such a patch, the upper and lower portions of this 'C' shaped barrier means are positioned against the vertebral endplates or overlying cartilage. As the pressure within the nucleus increases, these portions of the patch are pressurized against the endplates with an equivalent pressure, preventing the passage of materials around the barrier means. Dissecting a matching cavity prior to or during patch placement can facilitate use of such a 'C' shaped patch.

In another embodiment of the present invention, the patch may be used as part of a method to augment the intervertebral disc. In one aspect of this method, augmentation material or devices are inserted into the disc through a defect (either naturally occurring or surgically generated). Many suitable augmentation materials and devices are

discussed above and in t .ior art.. As depicted in Figure 9, the .er means is then inserted to aid in closing the defect and/or to aid in transferring load from the augmentation materials/devices to healthy tissues surrounding the defect. In another aspect of this method, the barrier means is an integral component to an augmentation device. As shown in Figures 10, 11A and 11B, the augmentation portion may comprise a length of elastic material that can be inserted linearly through a defect in the anulus. A region 300 of the length forms the barrier means of the present invention and can be positioned proximate to the interior aspect of the defect once the nuclear space is adequately filled. Barrier region 300 may then be affixed to surrounding tissues such as the AF and/or the neighboring vertebral bodies using any of the methods and devices described above.

While particular devices and methods have been described for sealing defects in body walls and repairing/augmenting the intervertebral disc, once this description is known, it will be apparent to those of ordinary skill in the art that other embodiments and alternative steps are also possible without deviating from the spirit and scope of the invention. Moreover, it will be apparent that certain features of each embodiment as well as features disclosed in each reference incorporated herein, can be used in combination with devices illustrated in other embodiments. Accordingly, the above description should be construed as illustrative, and not in a limiting sense, the scope of the invention being defined by the following claims.

What is claimed is:

1) A method of sealing a defect in the anulus fibrosis of a herniated intervertebral disc involving the steps of:

a) inserting a barrier means into the interior of said disc through an opening remote from said defect,

b) advancing said barrier means proximate the interior aspect of said defect,

c) deploying said barrier means such that it obstructs passage of materials from the interior of said disc into said defect.

2) A method of sealing a defect in the anulus fibrosis of a herniated intervertebral disc involving the steps of:

a) inserting a barrier means into the interior of said disc,

b) positioning said barrier means proximate to the interior aspect of said defect, said barrier means acting to obstruct passage of materials from the interior of said disc into said defect,

b) preventing said barrier means from coming through said defect by affixing at least that portion of said barrier means spanning said defect to a tissue proximate said defect.

3) A method of sealing a defect in the anulus fibrosis of a herniated intervertebral disc, said anulus fibrosis having multiple layers, said method involving the steps of:

a) inserting a first portion of a barrier means between at least two layers of said anulus fibrosis on a first side of said defect,

b) inserting a second portion of said barrier means between at least two layers of said anulus fibrosis on a second side of said defect, such that said barrier means spans said defect and is maintained in position at least in part by the anulus fibrosis on either side of said defect, said barrier means acting to obstruct passage of materials from the interior of said disc to the exterior of said disc through said defect.

4) Method of restoring the pressure distribution characteristics of an intervertebral disc following a herniation resulting from a defect in the anulus fibrosis, said disc having a nucleus pulposus on the interior of said disc, said method involving the step of:

a) inserting a barrier means into the interior of said disc,

b) positioning said barrier means proximate the interior aspect of said defect and in contact with said nucleus pulposus, said barrier means spanning said defect, said barrier means acting to transfer pressure from said nucleus pulposus to healthy portions of said anulus fibrosis surrounding said defect, said barrier means further acting to obstruct passage of materials from the interior of said disc into said defect.

5) A method of closing a defect in a ligamentous structure spanning two bones, said method involving the steps of:

a) positioning a barrier means proximate to said defect,

c) affixing at least a portion of said barrier means to at least one of said bones.

6) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a

first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) placing a barrier means on the interior aspect of said defect, said barrier means having an interior cavity, a wall surrounding said cavity, and an opening into said cavity,
b) passing a fixation means at least in part through said opening, into said cavity, through a portion of said wall, and into a tissue proximate said defect.

7) A method of sealing a defect as described in claim 6 wherein no aspect of said fixation means extends into said second anatomic region.

8) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) positioning a barrier means on the interior aspect of said defect,
b) passing a fixation means from said second anatomic region through a tissue surrounding said defect and into said barrier means.

9) A method of sealing a defect as described in claim 8 including the step of advancing said fixation means until no aspect of said fixation means remains within said second anatomic region.

10) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said interior aspect defining a region between said structure and a tissue within said first anatomic region, said wall and said tissue being in contact, said method involving the steps of:

a) inserting a dissection tool into said first anatomic region, said dissection tool comprising at least a barrier means removably affixed to said dissection tool,
b) dissecting a space between said wall and said tissue on said interior aspect of said defect with said dissection tool,
c) deploying said barrier means into said space,
d) removing said dissection tool.

11) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said defect further having a two dimensional open area, said method involving the steps of:

a) positioning a barrier means proximal to the interior aspect of said defect , said barrier means having a narrow dimension, said narrow dimension having a cross sectional area similar in size to or smaller than the open area of said defect,
b) inserting an enlarging means into said sealing means causing said cross sectional area to expand to a size greater than said open area,
c) securing said enlarging means to a tissue proximate said defect with a fixation means.

12) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said defect further having a two dimensional open area, said method involving the steps of:

a) positioning a barrier means proximate to the interior aspect of said defect, said barrier means comprising an expandable sealing means, a fixation means, and an expansion means, said sealing means being positioned proximate to said interior aspect of said defect in a compressed state, said fixation means being affixed to said sealing means and capable of fixing to tissue proximate to said sealing means, said expansion means being in contact with said sealing means and being capable of forcibly expanding said sealing means,

c) expanding said sealing means to an expanded state with said expansion means whereby said integral fixation means become secured to tissues surrounding said sealing means.

13) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) placing a barrier means comprising a sealing means on the interior aspect of said defect, said sealing means having an interior cavity, a wall surrounding said cavity, and an opening into said cavity,

b) passing a fixation means at least in part through said opening, into said cavity, through said wall, and into a tissue proximate said defect such that no aspect of said fixation means extends into said second anatomic region,

c) inserting an enlarging means into said sealing means causing said sealing means to expand to an expanded state.

14) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said defect further having a two dimensional open area, said method involving the steps of:

a) positioning a barrier means proximate to the interior aspect of said defect

b) constricting said defect's open area to a reduced area by passing energy into the tissues surrounding said defect.

15) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said interior aspect defining a region between said structure and a tissue within said first anatomic region, said wall and said tissue being in contact said method involving the steps of:

a) positioning a barrier means proximate to the interior aspect of said defect and in contact with said tissue, said sealing means further being in contact with a thermal element capable of heating said sealing means and surrounding tissues,

b) heating said barrier means and surrounding tissues with said thermal element,

c) removing said thermal element.

16) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) positioning an expandable barrier means in a compressed state proximate to the interior aspect of said defect, said barrier means being in contact with a thermal element capable of heating said barrier means and surrounding tissues,
b) expanding said sealing means to an expanded state,
c) heating said barrier means and surrounding tissues with said thermal element,
d) removing said thermal element.

17) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) positioning an expandable barrier means in a compressed state proximate to the interior aspect of said defect, said barrier means being in contact with a thermal element capable of both heating said barrier means and surrounding tissues and expanding said barrier means to an expanded state,
b) expanding said barrier means to an expanded state using said thermal element,
c) heating said barrier means and surrounding tissues with said thermal element,
d) removing said thermal element.

18) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) positioning an expandable barrier means in a compressed state proximate to the interior aspect of said defect, said barrier means having an interior cavity and an opening leading from the exterior of said barrier means into said cavity,
b) positioning an expanding means within said cavity, said expanding means capable of expanding said barrier means to an expanded state,
c) expanding said barrier means to said expanded state,
c) heating said barrier means and surrounding tissues.

19) A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said method involving the steps of:

a) inserting a barrier means at least in part into said defect, whereby at least a portion of said barrier means lies between said interior and exterior aspects, said barrier means being in contact with a thermal element capable of heating said sealing means and surrounding tissues,
b) heating said barrier means and surrounding tissues with said thermal element,
c) removing said thermal element.

20) A method as described in claims 1-19 wherein said method includes the steps of adding augmentation material or devices to either said first anatomic region or said interior of said intervertebral disc.

21) A method as described in claims 1-19 wherein said barrier means comprises a portion of an augmentation device capable of supporting load transferred through said first anatomic region or said interior of said intervertebral disc.

22) A method as described in claims 6, 8, and 10-19 wherein said first anatomic region includes the region defined by the anulus fibrosis and the superior and inferior vertebral endplates of an intervertebral disc and wherein said second anatomic region is any region beyond the outer-most periphery of the anulus fibrosis.

23) A method as described in claim 5 wherein said ligamentous structure is the anulus fibrosis of an intervertebral disc and said bones are two vertebrae.

24) An implantable barrier means adapted to seal an opening into a body space or cavity, said device comprising:

a) a semi-rigid core, said core having a length and a thickness, wherein said length is substantially greater than said thickness,
b) a flexible sealing material, said sealing material covering at least a portion of said length of said core.

25) A barrier means suitable for sealing a defect in the wall of a pressurized body cavity, said barrier means comprising an elongated sealing means, said sealing means having at least two regions, a first stiffer region and a second less stiff region wherein said first region can be positioned to span the interior aspect of said defect, wherein said second region extends beyond said defect on said interior aspect of said cavity.

26) A barrier means suitable for sealing a defect in the wall of a pressurized body cavity, said barrier means comprising an elongated sealing means, said sealing means having at least two regions, a first stiffer region and a second less stiff region wherein said first region can be positioned to span the interior aspect of said defect, wherein said second region extends beyond the periphery of said first region on the interior aspect of said cavity, said device further comprising a fixation region located within said stiffer region, said fixation region allowing secure fixation of said device to a tissue proximate said defect.

27) A disc augmentation prosthesis that acts to bear loads passing through an intervertebral disc and to seal a defect in the anulus fibrosis of said disc, said defect having an interior aspect facing the interior of said disc, said disc augmentation prosthesis comprising:

a) an augmentation region dimensioned to be inserted into the interior of said disc through a defect in said anulus fibrosis, said augmentation region having a compliant structure that fills a majority of the interior of said disc,
b) a barrier means region dimensioned to extend across the interior aspect of said defect and obstruct the passage of material from the interior of said disc into said defect, said barrier means region further having a fixation region suitable for securing said barrier means region to surrounding tissues.

28) An implantable barrier means adapted to seal a defect in a structure separating two anatomic regions of a body, said defect allowing passage of material between said two anatomic regions, said barrier means comprising:

a) an expandable sealing means dimensioned to be inserted through said defect, said sealing means having at least one interior cavity and an opening leading into said cavity,
b) a single expansion means, said expansion means dimensioned to pass into said cavity through said opening, said expansion means capable of expanding said sealing means to an expanded dimension that cannot pass through said defect, wherein said expanded sealing means acts to seal said defect and prevent the passage of materials there through.

29) An implantable barrier means adapted to seal a defect in a structure separating two anatomic regions of a body, said defect further having a two dimensional open area, said barrier means comprising:

a) a flexible sealing means, said sealing means having a cross sectional area equal to or smaller than said open area to facilitate insertion into said body cavity,
b) a rigid core, said core having a cross sectional area equal to or less than said open area to facilitate insertion into said cavity, said core adapted to be inserted into said flexible sealing means, wherein said barrier means has a minimum cross sectional area when assembled within said body cavity, said minimum cross sectional area being greater than said open area.

30) An implantable barrier system adapted to seal a defect in a structure separating two anatomic regions of a body, said defect further having a two dimensional open area, said barrier system comprising:

a) an expandable sealing means having an exterior surface, an interior cavity, and at least one opening leading from said exterior surface to said cavity,
b) an expansion means, said expansion means dimensioned to pass into said cavity through said opening, said expansion means capable of expanding said sealing means to an expanded dimension greater than said open area,
c) a fixation means, said fixation means capable of securing said barrier system to surrounding tissues.

31) An implantable barrier means adapted to seal a defect in a structure separating two anatomic regions of a body, said defect further having a two dimensional open area, said barrier means comprising:

a) an expandable sealing means having an exterior surface, an interior cavity, and at least one opening leading from said exterior surface to said cavity,
b) an expansion means, said expansion means dimensioned to pass at least in part into said cavity through said opening, said expansion means capable of expanding said sealing means to an expanded dimension greater than said open area of said defect, said expansion means having a fixation region allowing the secure fixation of said expansion means to tissues surrounding said defect using a fixation means.

32) An implantable barrier means as described in claim 27 wherein said fixation region extends to said exterior surface.

33) A system for sealing a defect in a soft tissue of a living being, said system comprising:

a) a barrier means formed at least in part from a material capable of adhering to tissues surrounding said defect upon the application of heat to said barrier means and said surrounding tissues,

b) a deployment means in intimate contact with said barrier means, said deployment means comprising at least a thermal element capable of increasing the temperature of said patch and said tissues.

34) A system for sealing a defect in a soft tissue of a living being, said system comprising:

a) an expandable barrier means formed at least in part from a material capable of adhering to tissues surrounding said defect upon the application of heat to said barrier means and said surrounding tissues,

b) a deployment means in intimate contact with said barrier means, said deployment means comprising at least an expansion means capable of expanding said barrier means to an expanded state and a thermal element capable of increasing the temperature of said barrier means and said surrounding tissues.

35) A system for sealing a defect in a soft tissue of a living being, said system comprising:

a) a barrier means formed at least in part from a material capable of adhering to surrounding tissues upon the application of heat to said barrier means and said surrounding tissues, said barrier means having an interior cavity,

b) a deployment means located at least in part within said interior cavity, said deployment means comprising at least a thermal element capable of increasing the temperature of said barrier means and said surrounding tissues.

36) A system for sealing a defect in a soft tissue of a living being, said system comprising:

a) an expandable barrier means formed at least in part from a material capable of adhering to surrounding tissues upon the application of heat to said barrier means and said surrounding tissues, said barrier means having an interior cavity,

b) a deployment means, said deployment means positioned at least in part within said interior cavity, said deployment means comprising at least a balloon capable of inflating from a compressed state to an expanded state, and a thermal element capable of increasing the temperature of said barrier means and said surrounding tissues.

37) A system for sealing a defect in a soft tissue of a living being, said system comprising:

a) an expandable barrier means formed at least in part from a material capable of adhering to surrounding tissues upon the application of heat to said barrier means and said surrounding tissues, said barrier means having an interior cavity,

b) a deployment means comprising at least a balloon capable of inflating from a compressed state to an expanded state and of increasing the temperature of said barrier means and said surrounding tissues, said balloon being movably positioned within said interior cavity such that said balloon can be removed from said interior cavity.

38) A system, device or barrier means as described in claims 24-37 wherein said sealing means is constructed from a material including any of the following in a woven or non-woven form – Nylon, Marlex, collagen, PTFE, e-PTFE, or Dacron.

39) A system, device or barrier means as described in claims 24-26 and 28-32 wherein said core, stiffer region, or expansion means is constructed from a material including any of the following – steel, nickel-titanium alloy, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

40) A core or expansion means as described in claim 39 wherein said material is formed into a solid rod.

41) A core or expansion means as described in claim 39 wherein said material is formed into a tube

42) A core or expansion means as described in claim 39 wherein said material is formed into an elongated coil.

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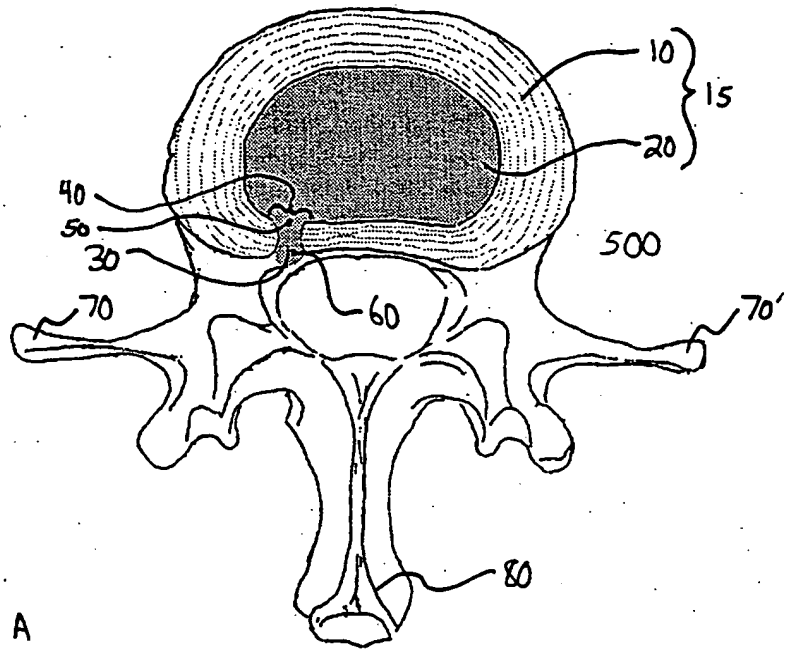
	5,366,460	Eberbach	(barrier)
	5,368,602	de la Torre	(barrier)
	5,383,477	DeMateeis	(barrier)
	5,531,759	Kensey et al.	(barrier)
	5,545,178	Kensey et al.	(barrier)
	5,725,577	Saxon	(barrier)
	5,743,917	Saxon	(barrier)
	5,766,246	Mulhauser et al.	(barrier)
	5,769,864	Kugel	(barrier)
	5,916,225	Kugel	(barrier)
	5,935,147	Kensey et al.	(barrier)
	5,954,767	Pajotin et al.	(barrier)
	5,972,007	Sheffield et al.	(barrier)



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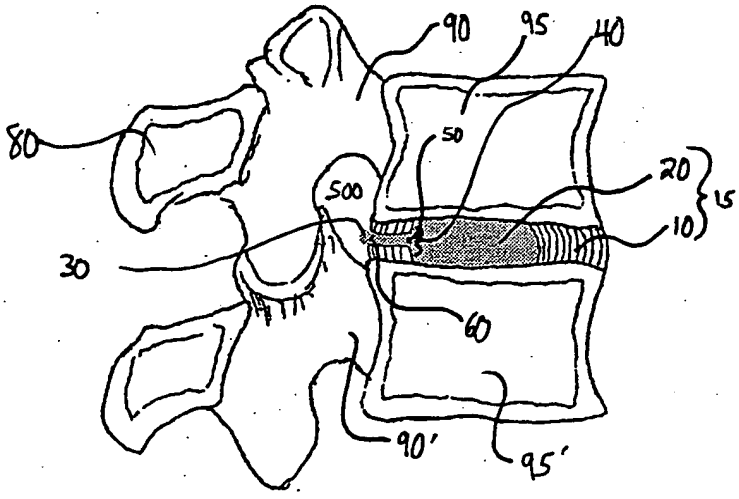

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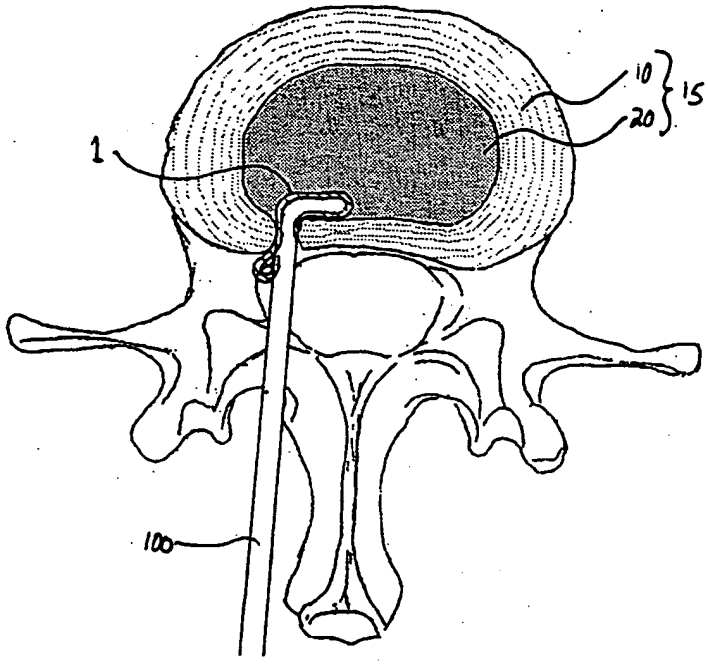

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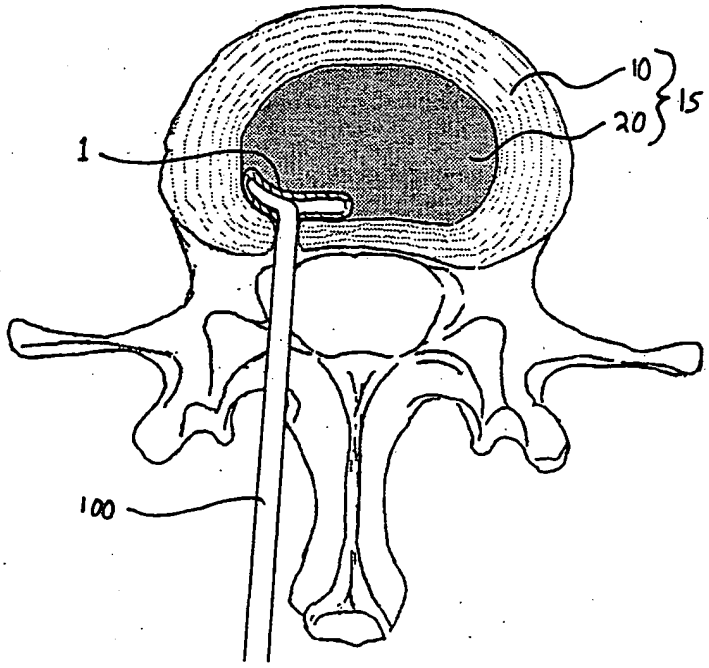

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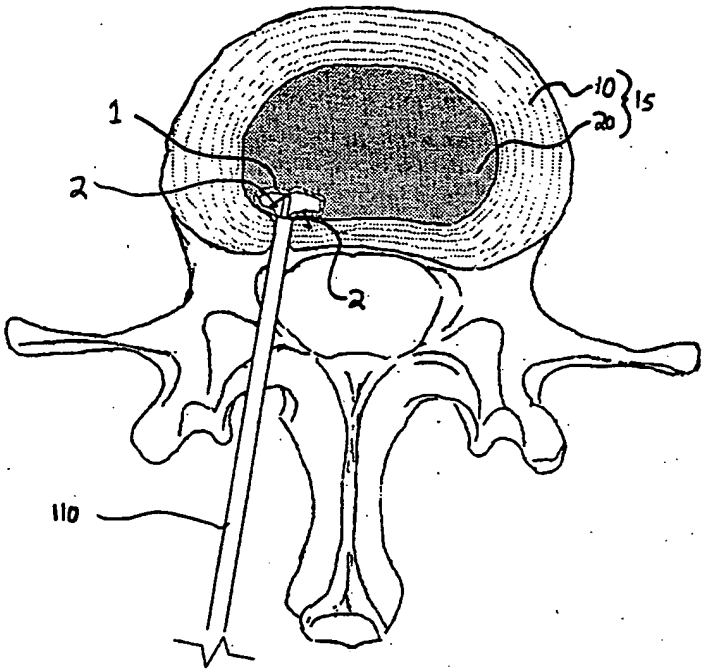

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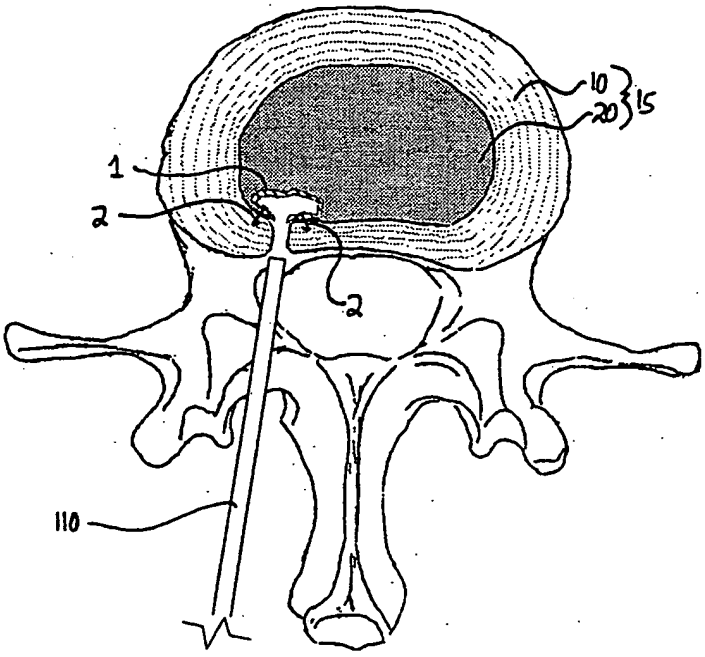

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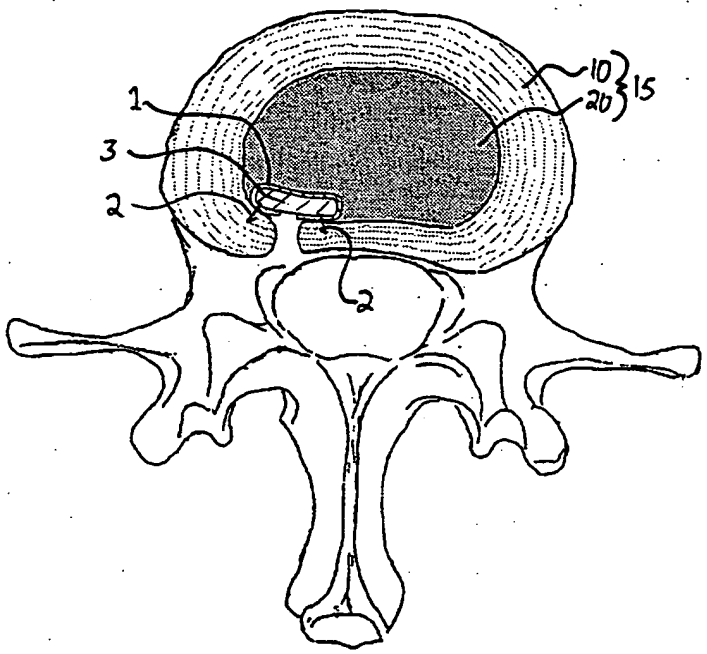

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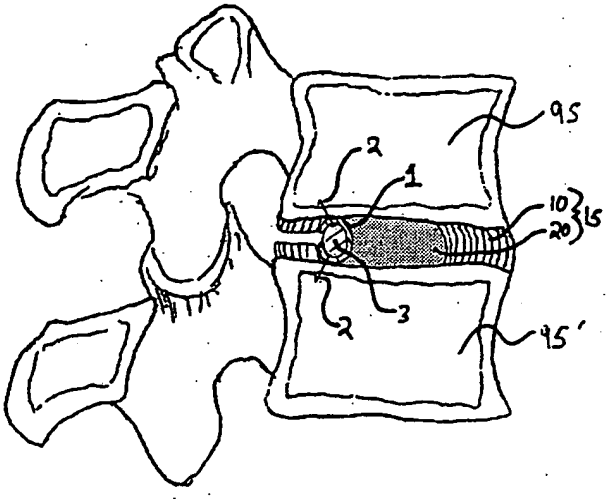

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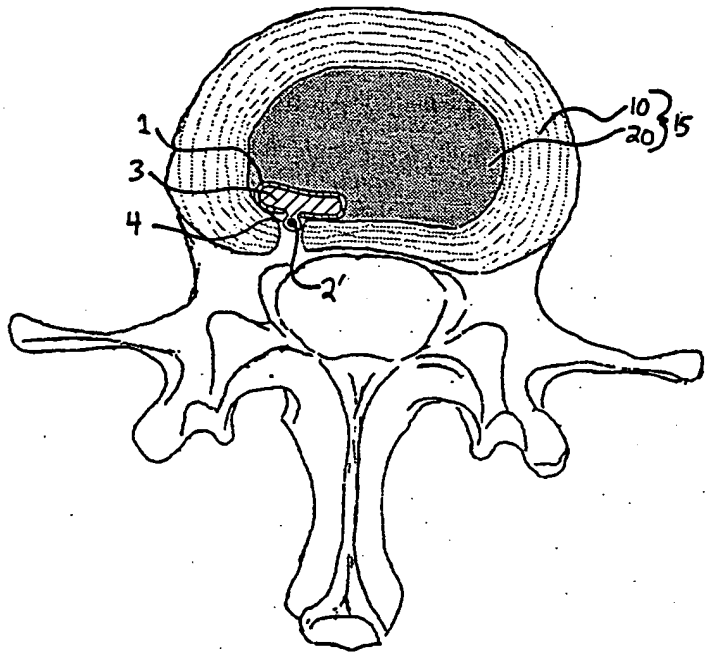

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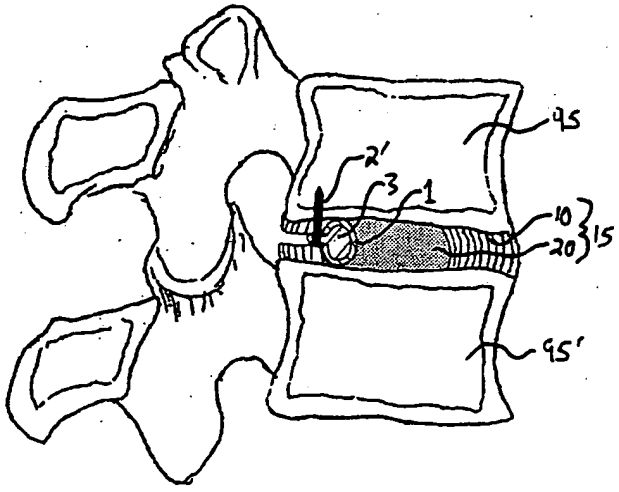

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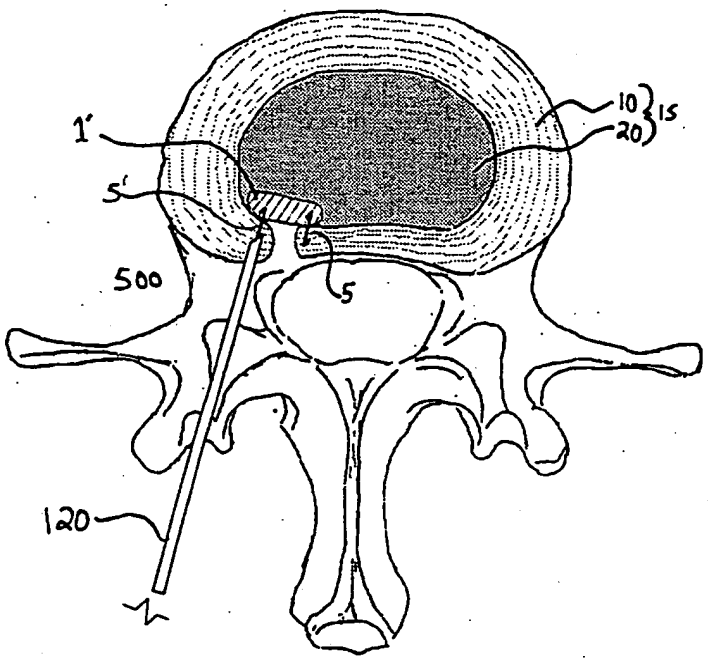

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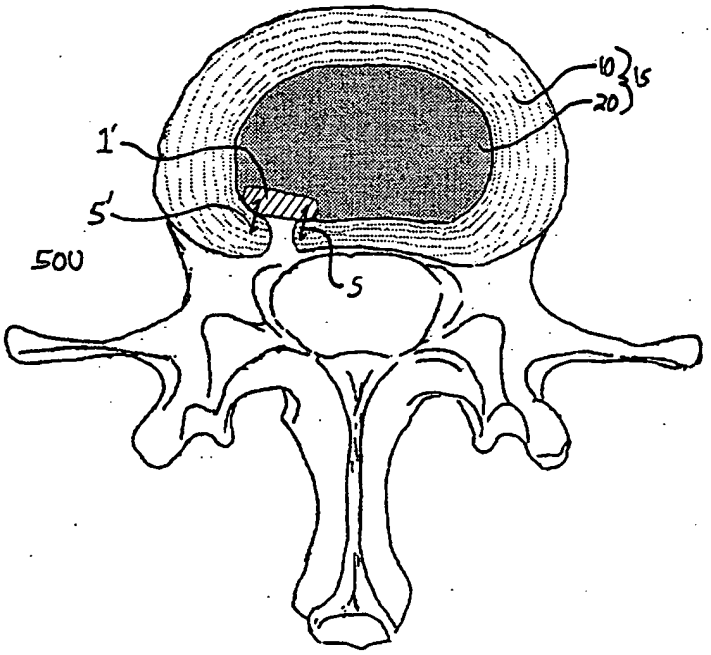

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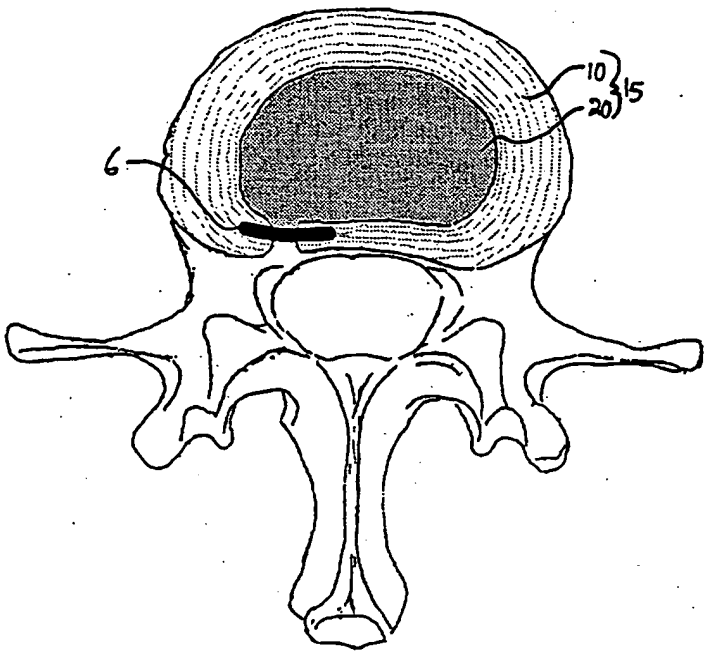

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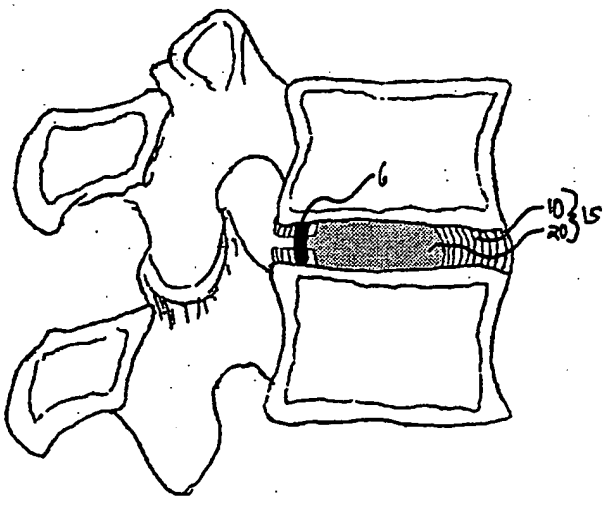

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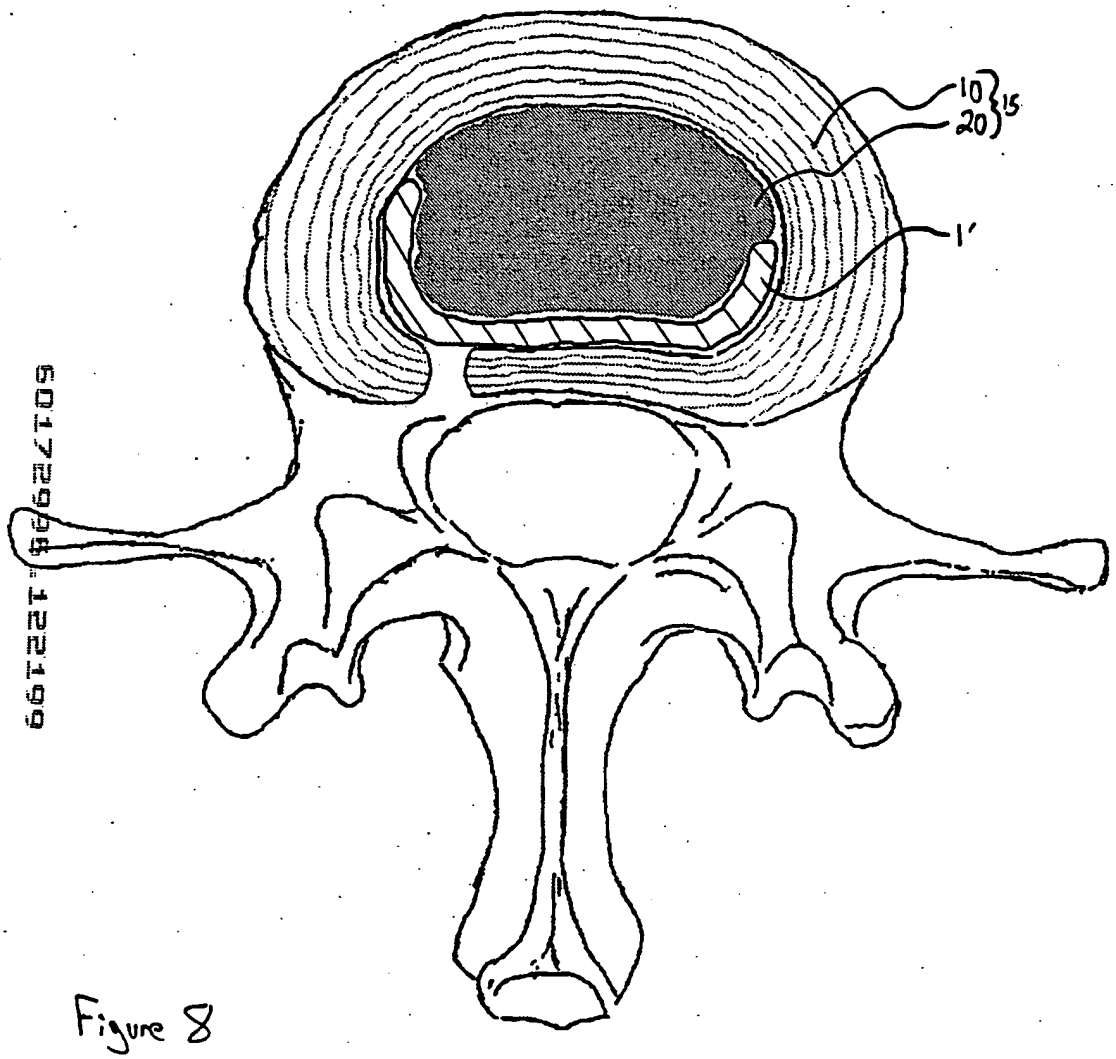

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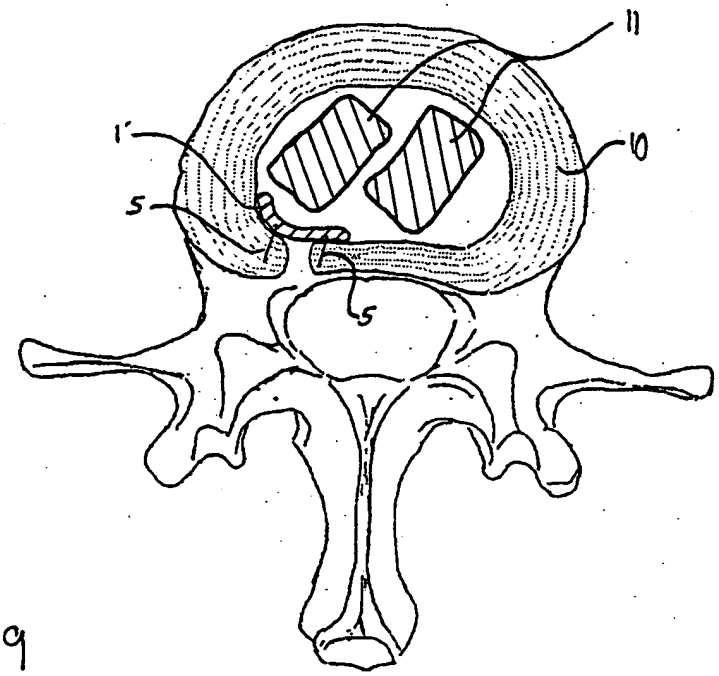

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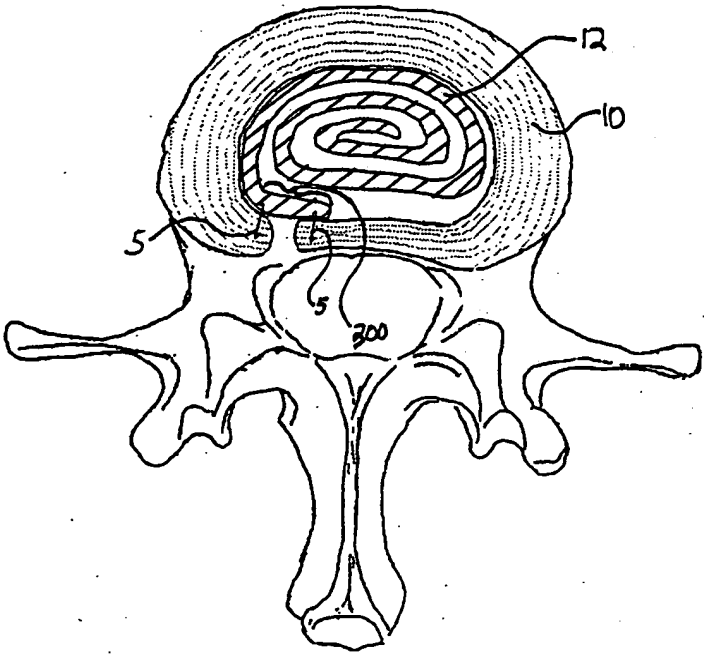

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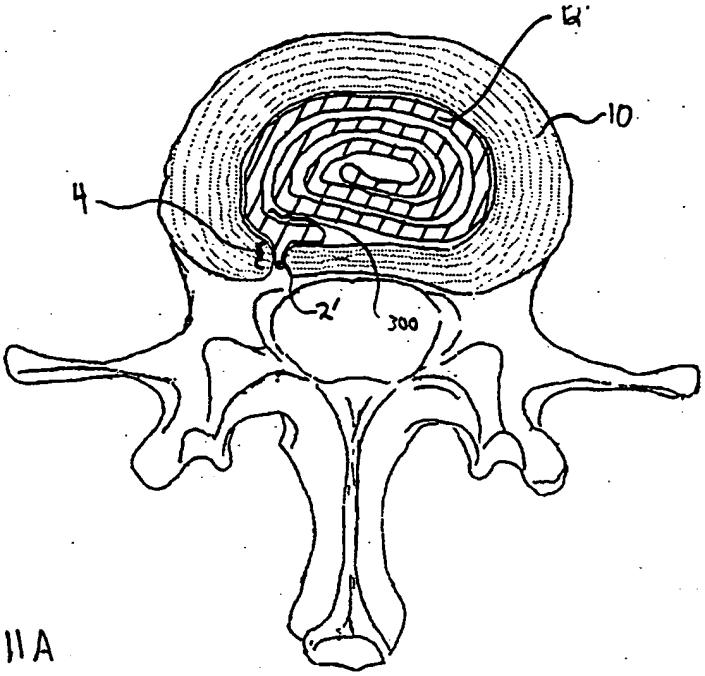

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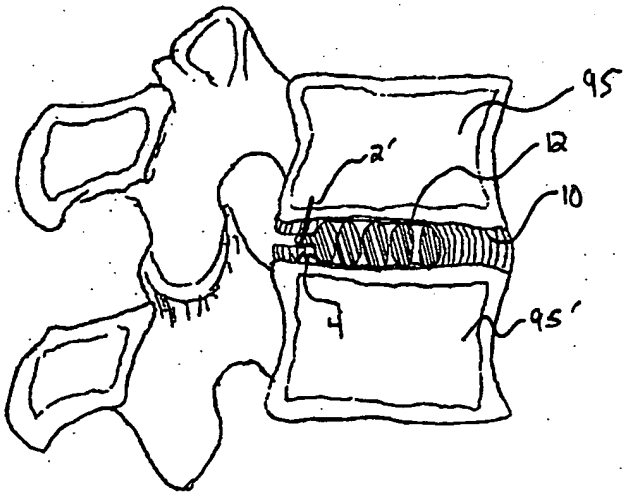

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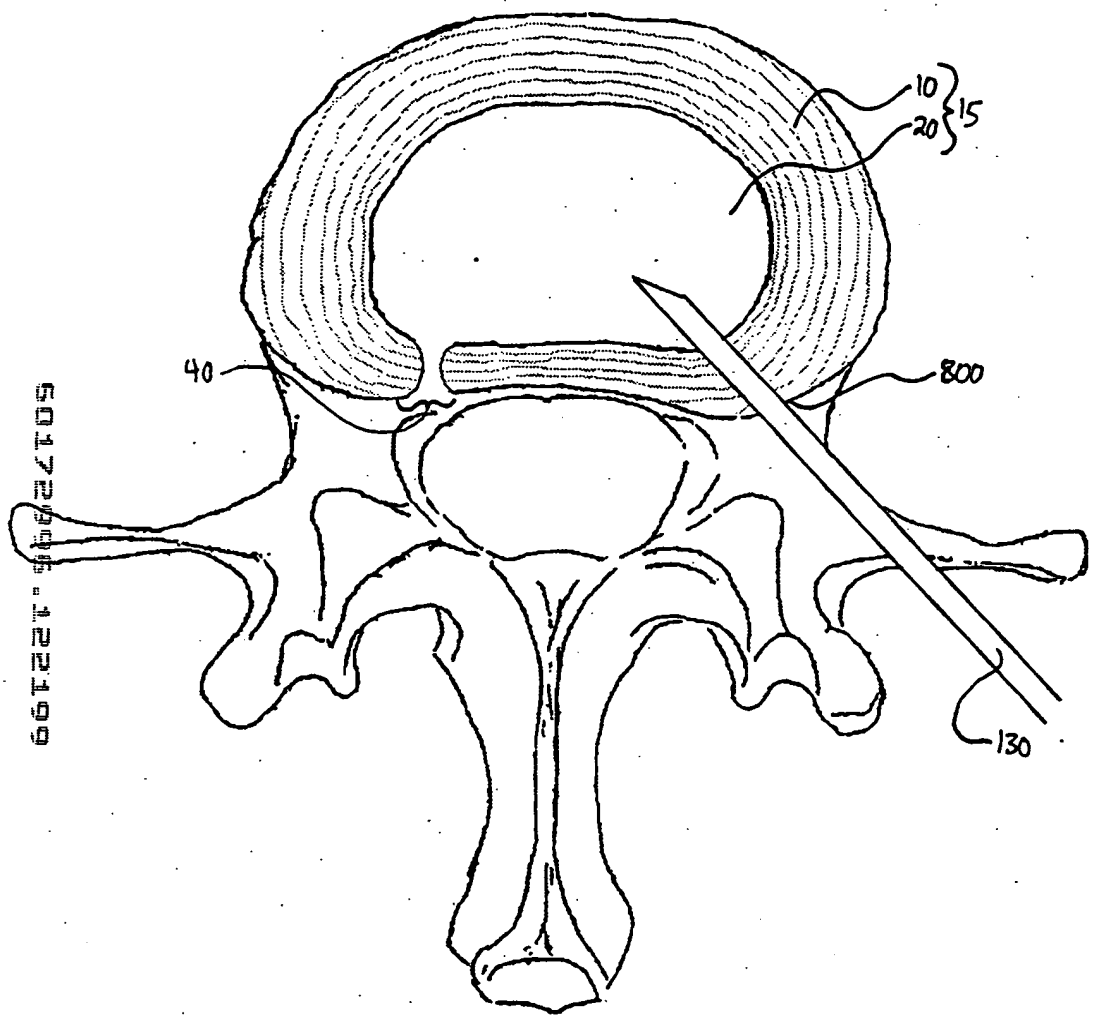

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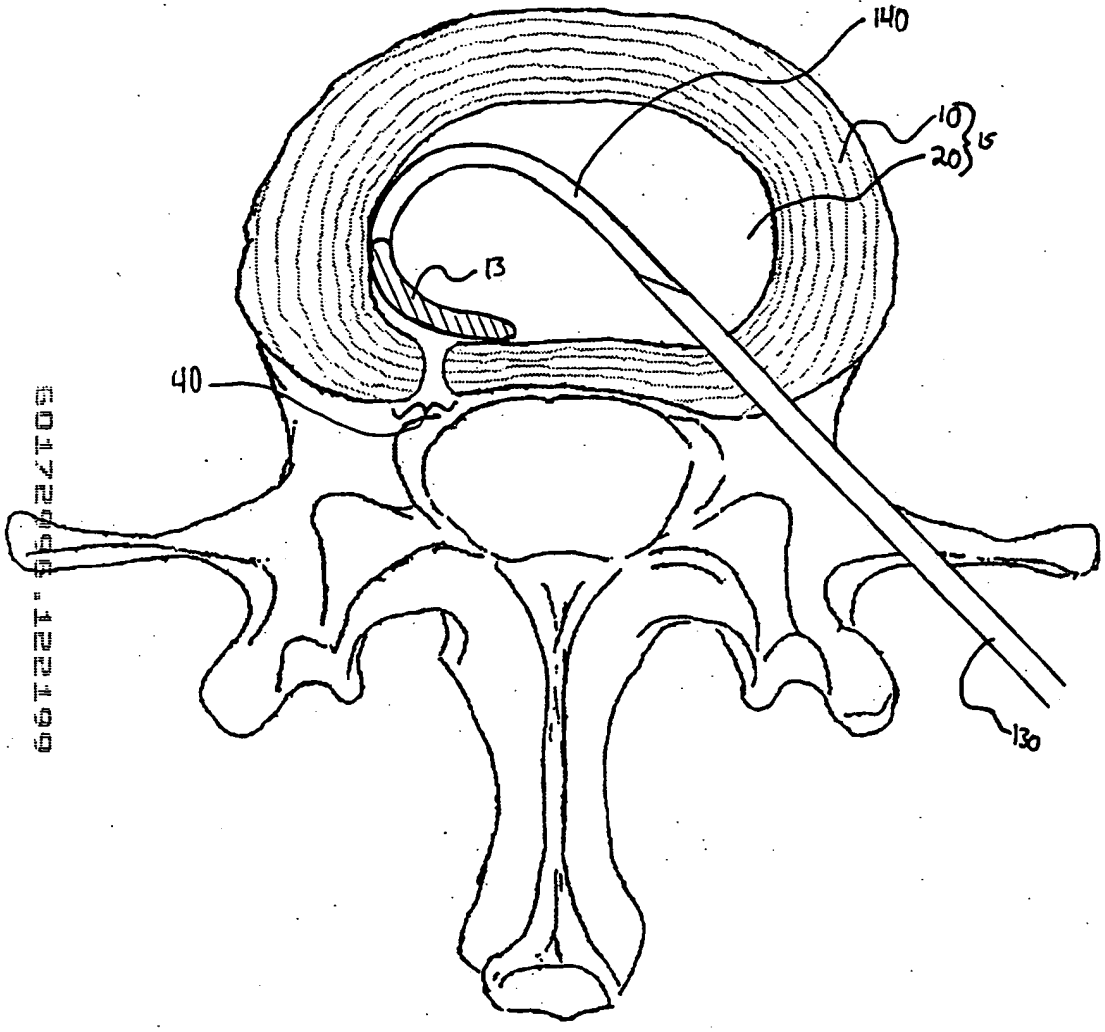

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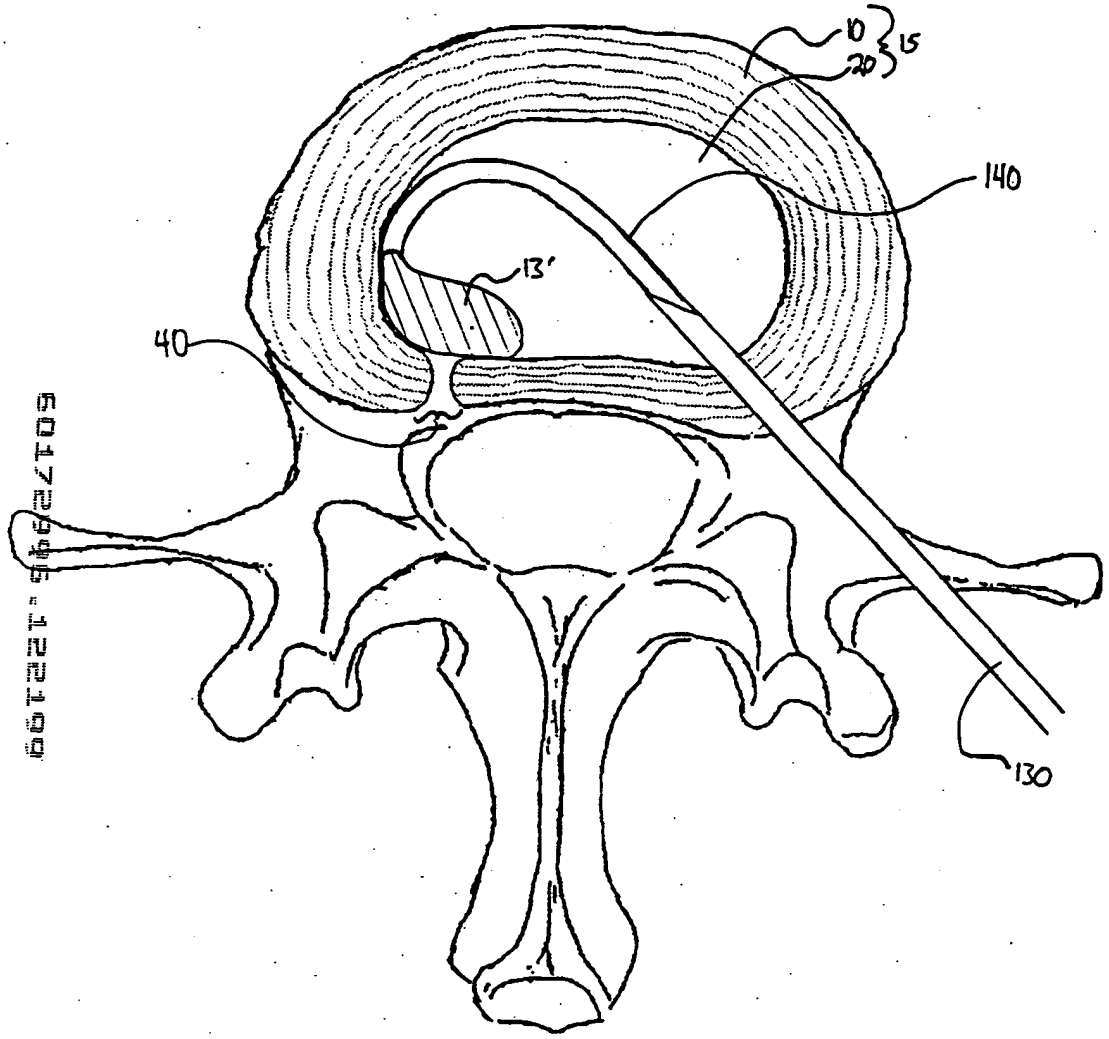

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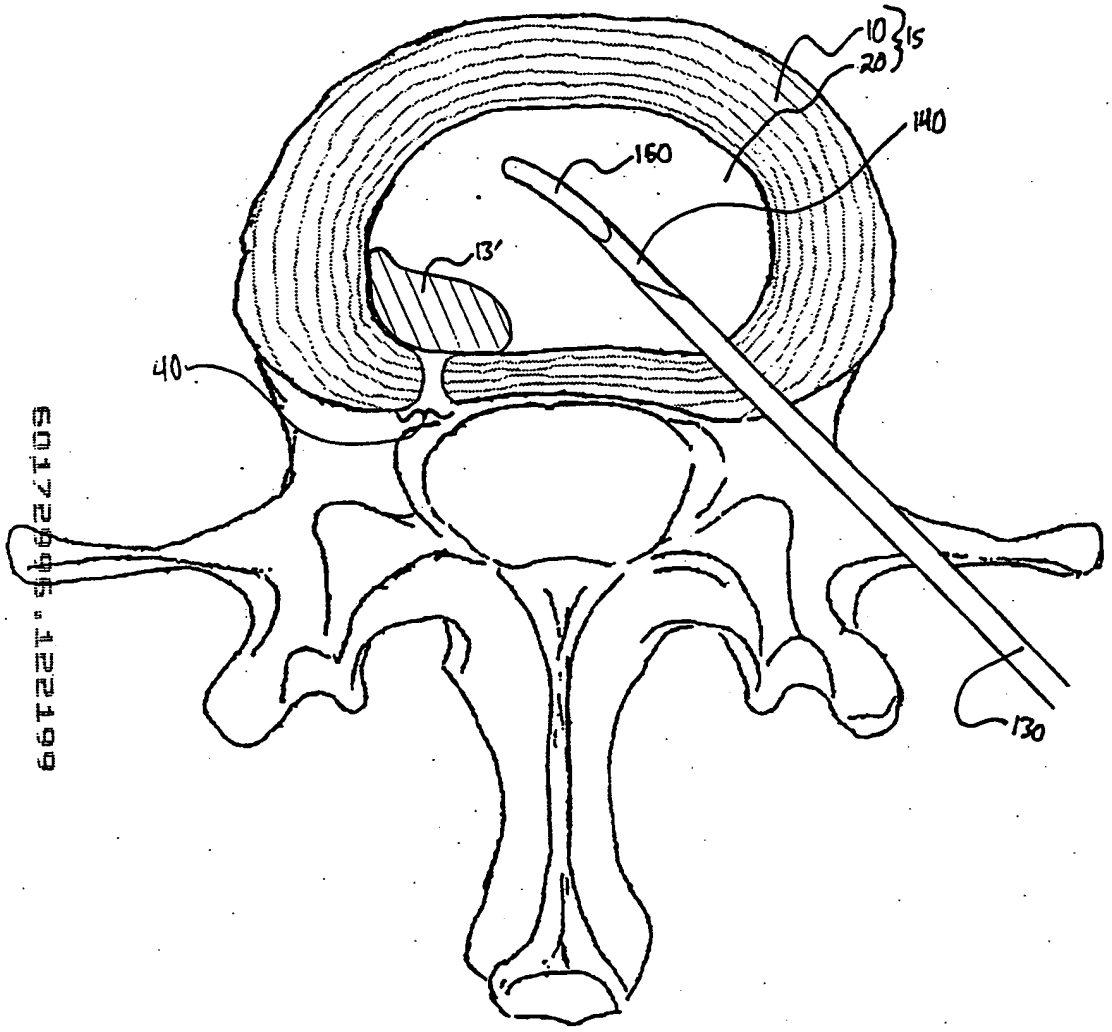

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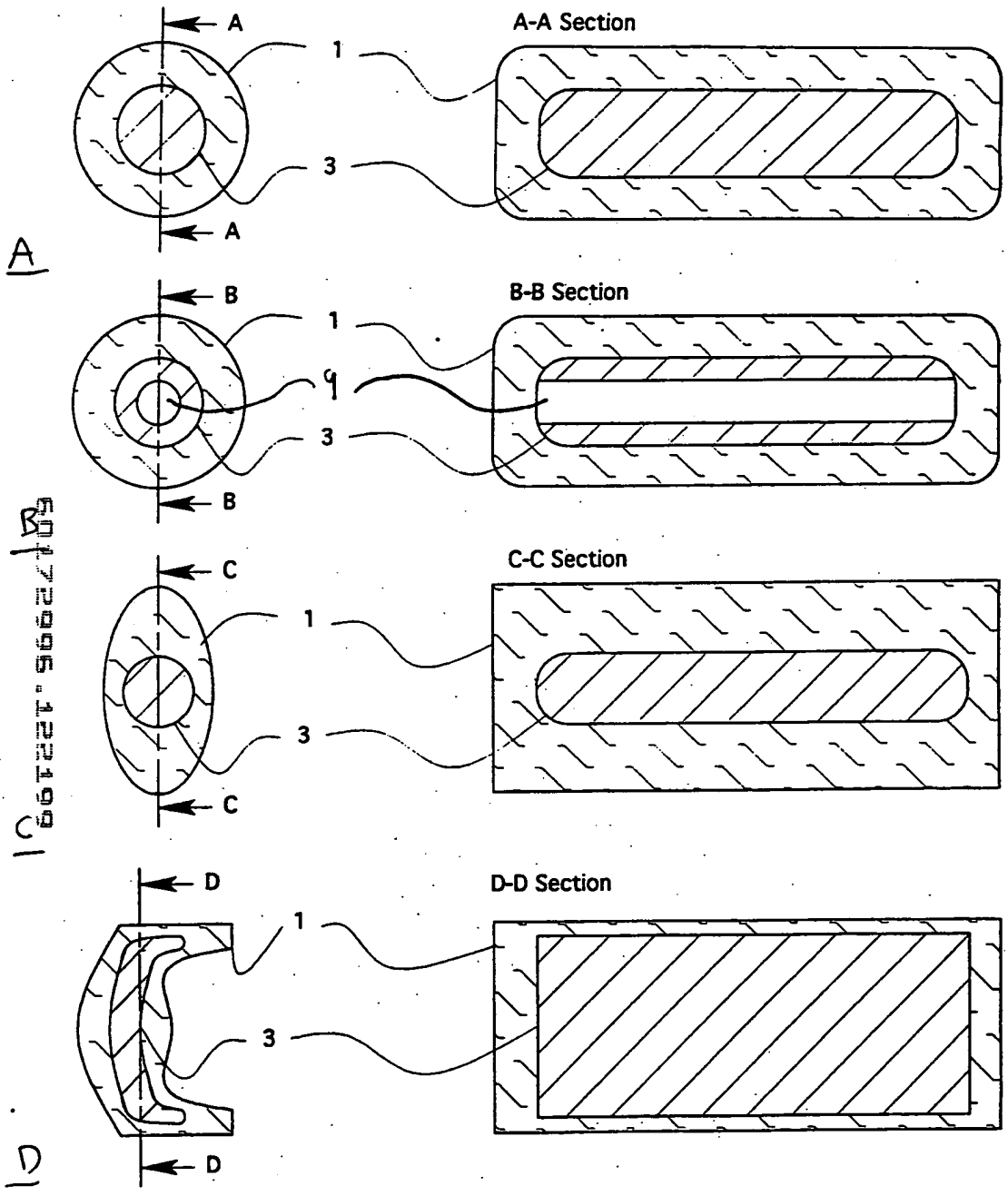
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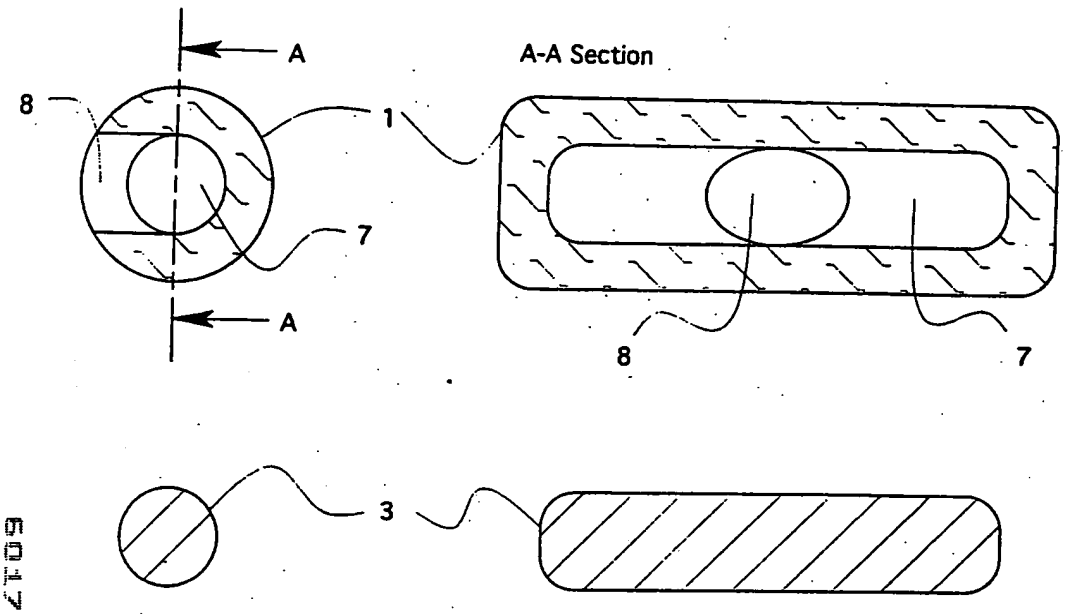
Figure 13



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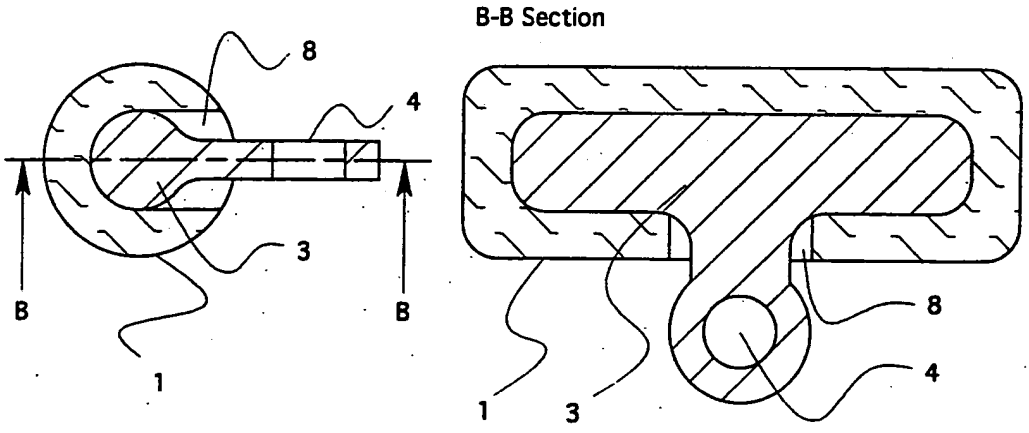

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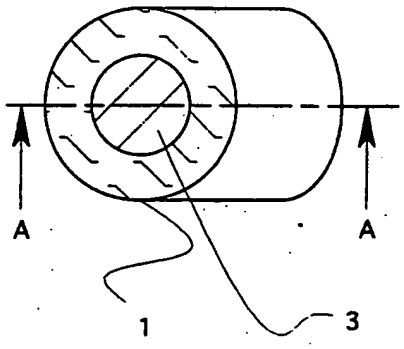

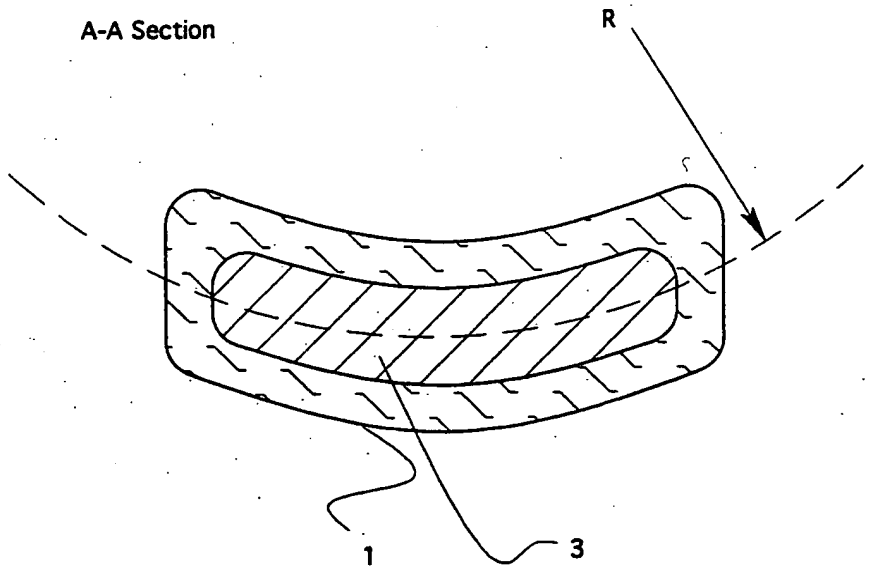

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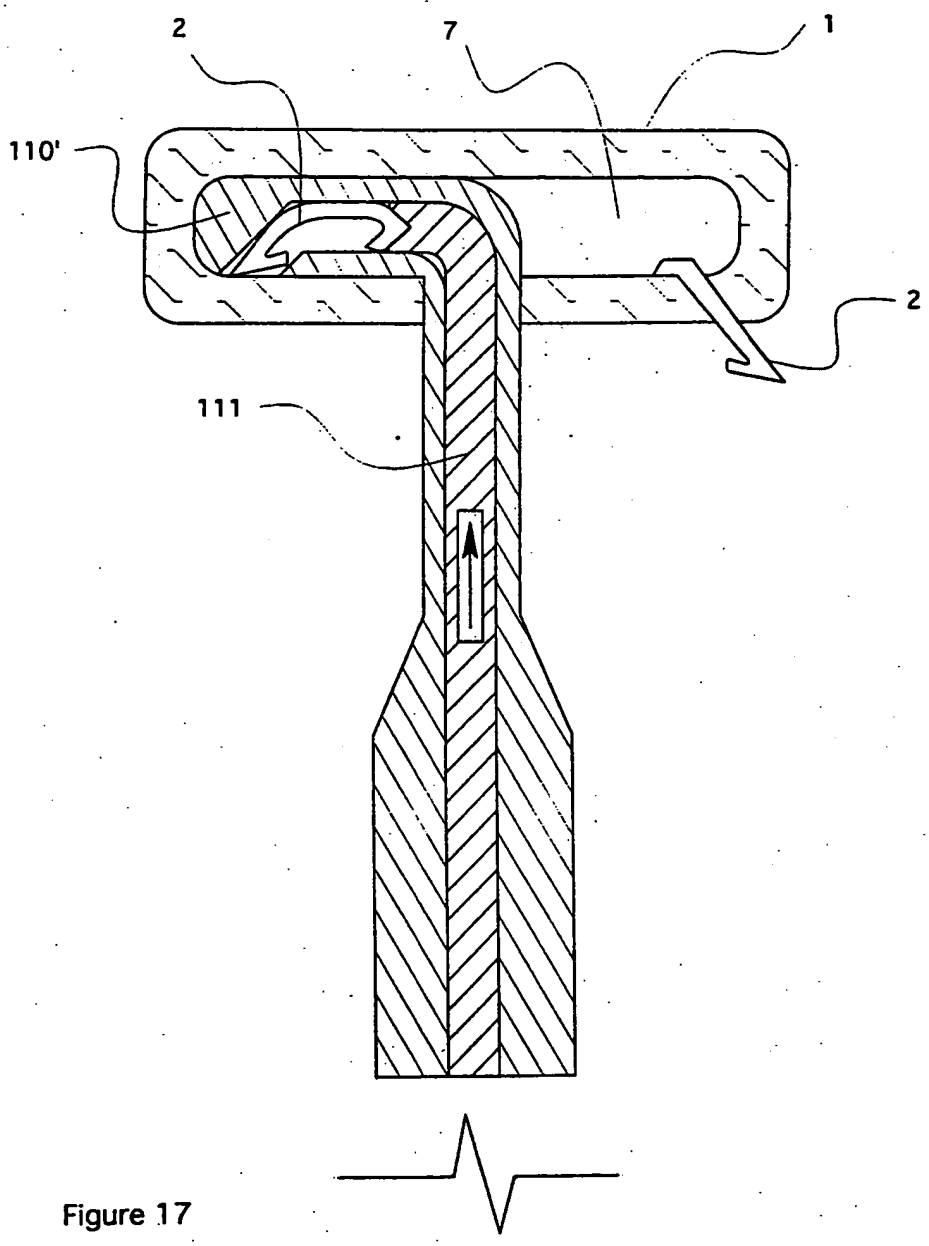

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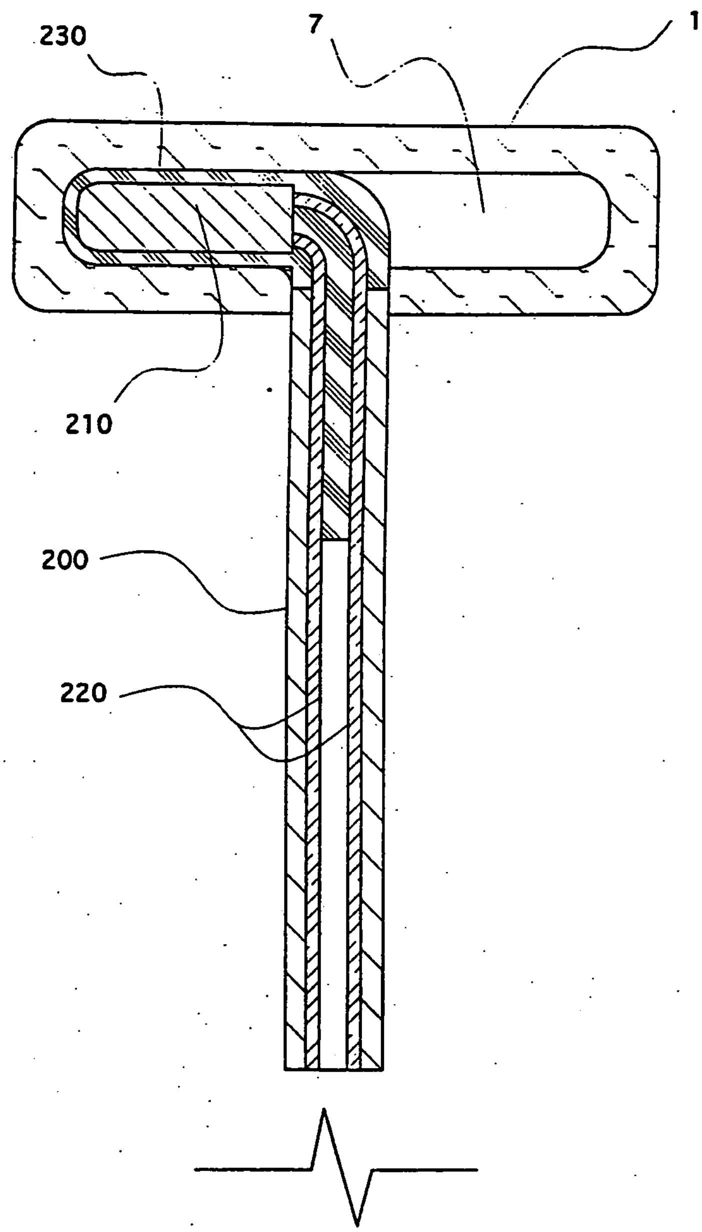

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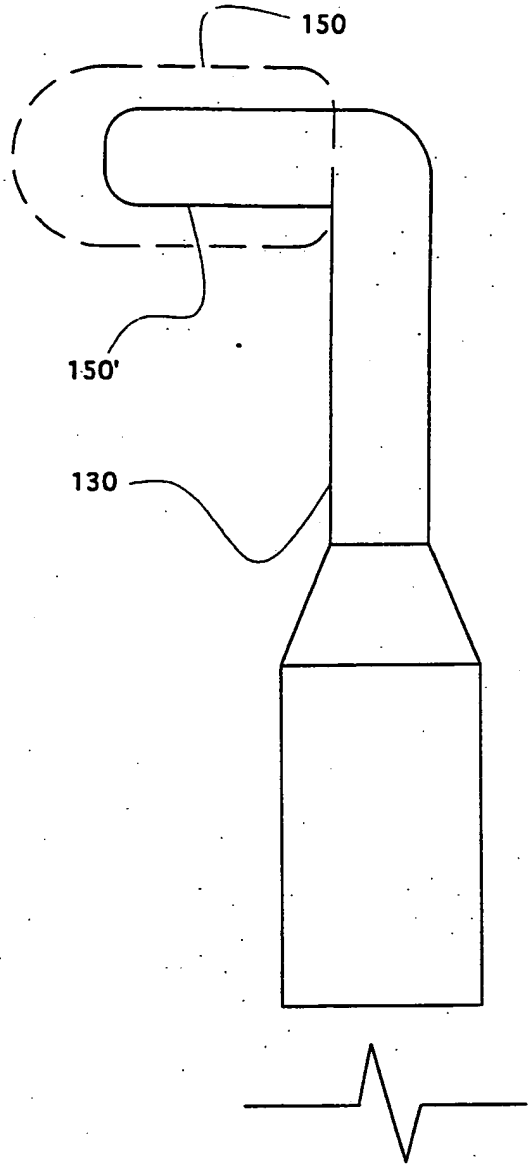

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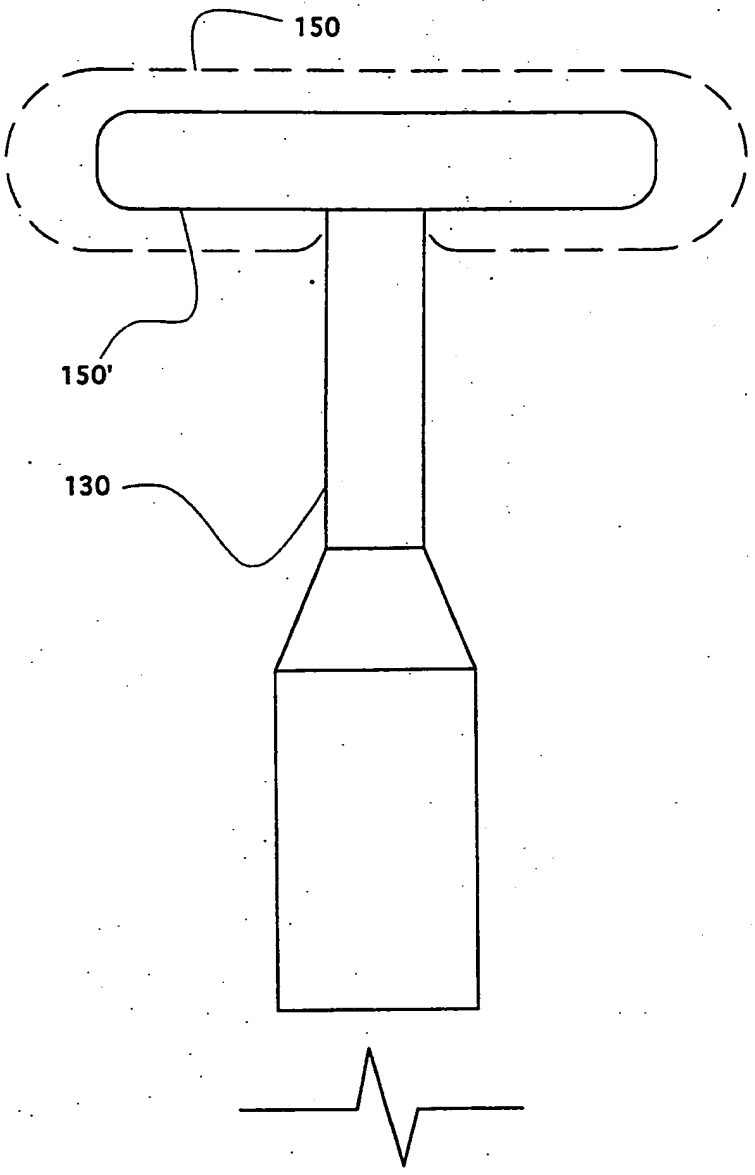

Figure 20

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PATENT APPLICATION
Attorney's Docket No 3005 1000-000
VIA FACSIMILE

TOH/JJD
12/18/00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/149,490
Filed:	August 18, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-005

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/161,085
Filed:	October 25, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-006

Applicants:	Gregory H. Lambrecht
U.S. Application No.:	60/172,996
Filed:	December 21, 1999
Title:	DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION
Attorney Docket No.:	3005.1000-007

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60/149,490
60/161,085
60/172,996

Respectfully submitted,
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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REQUEST FOR ACCESS OF ABANDONED APPLICATION UNDER 37 CFR 1.14(a)

In re Application of	
Application Number: 60/172,996	Filed: 12/21/99
Group Art Unit:	Examiner:

Paper No. #3

Assistant Commissioner for Patents
Washington, DC 20231

I hereby request access under 37 CFR 1.14(a)(3)(iv) to the application file record of the above-identified ABANDONED application, which is: (CHECK ONE)

X (A) referred to in United States Patent Number 6,425,919, column Face.

___ (B) referred to in an application that is open to public inspection as set forth in 37 CFR 1.11, i.e., Application No. _____, filed _____, on page _____ of paper number _____,

___ (C) an application that claims the benefit of the filing date of an application that is open to public inspection, i.e., Application No. _____, filed _____, or

___ (D) an application in which the applicant has filed an authorization to lay open the complete application to the public.

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Unit: _____

US006425919B1

(12) **United States Patent**
Lambrecht

(10) **Patent No.: US 6,425,919 B1**
(45) **Date of Patent: Jul. 30, 2002**

(54) **DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION**

(75) Inventor: **Gregory H Lambrecht**, Natick, MA (US)

(73) Assignee: **Intrinsic Orthopedics, Inc.**, Wilmington, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1 day.

(21) Appl. No.: **09/608,797**

(22) Filed: **Jun. 30, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/149,490, filed on Aug. 18, 1999, provisional application No. 60/161,035, filed on Oct. 25, 1999, and provisional application No. 60/172,996, filed on Dec. 21, 1999.

(51) **Int. Cl.**[7] **A61F 2/44**
(52) **U.S. Cl.** **623/17.16**
(58) **Field of Search** 623/17.16; 128/898

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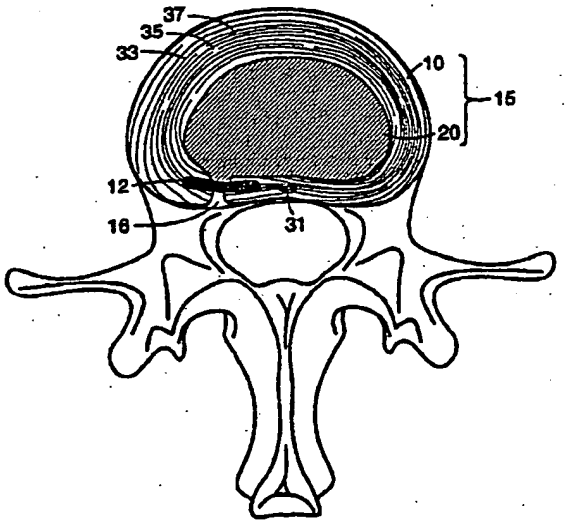
Primary Examiner—Corrine McDermott
Assistant Examiner—Thomas Barrett
(74) *Attorney, Agent, or Firm*—Sean Kavanaugh; Intrinsic Orthopedics, Inc.; Gerard Von Hoffmann

(57) **ABSTRACT**

A disk herniation constraining device for implantation into a vertebral disk can include a support member for support of a herniated portion of a disk. The support member can be connected to an anchor. The constraining device can include the insertion of augmentation material within the disk. A defect in the annulus of a disk can be closed using a prosthesis such as a barrier.

The barrier can be placed between the annulus and the nucleus of the disk. The barrier can include a sealant and an enlarger. The barrier can be implanted into the disk using a delivery cannula, an advancer and at least one control filament to control the positioning of the barrier over the defect. A stiffening element can be included within the barrier to impart stiffness to the barrier.

20 Claims, 64 Drawing Sheets



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FEE DETERMINATION			
O.I.P.E. CLASSIFIER		21	1/5/00
FORMALITY REVIEW	DXL	6514	2/2/00
RESPONSE FORMALITY REVIEW			

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PATENT APPLICATION

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60/172996

12/21/99

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	2. Power to inspect	12-24-00
	3. Request Publication	8/1/02
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